

**UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF OHIO
EASTERN DIVISION**

IN RE SOTERA HEALTH COMPANY SECURITIES REGULATION))))))))	CASE NO. 1:23-cv-143 JUDGE CHARLES E. FLEMING MEMORANDUM OPINION AND ORDER
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This is a securities fraud class action brought on behalf of those who purchased Sotera Health Company common stock between November 19, 2020 and September 19, 2022 (the “Class Period”). Plaintiffs based their claims on violations of Section 10(b) of the Securities Exchange Act of 1934, 15 U.S.C. § 78a *et seq.* (the “Exchange Act”), Rule 10b-5, which was promulgated thereunder, and Section 20(a) of the Exchange Act. They also allege violations of Section 11 of the Securities Act of 1933, 15 U.S.C. § 77a *et seq.* (the “Securities Act”), Section 12(a)(2) of the Securities Act, and Section 15 of the Securities Act. In essence, Plaintiffs claim that Defendants made a series of false and/or misleading statements concerning its compliance with permits and applicable regulations, certain litigation and the material risks associated therewith, and its efforts to control emissions of the chemical ethylene oxide (“EO” or “EtO”), which Sotera’s subsidiary, Sterigenics, uses to sterilize medical equipment.

Defendants have filed a Motion to Dismiss Consolidated Class Action Complaint (“Complaint”), presenting the Court with the following issues: (1) whether Plaintiffs’ Securities Act claims must be pleaded with particularity under Fed. R. Civ. P. 9(b), when the claims sound in fraud but specifically disclaim alleging fraud; (2) whether the Complaint pleads actionable, material misstatements and omissions under the Exchange Act with particularity consistent with Fed. R. Civ. P. 9(b) and the Private Securities Litigation Reform Act, 15 U.S.C. § 78u-4 *et seq.*

(“PSLRA”); (3) whether Securities Act Plaintiffs have adequately pleaded their Section 11 claims; (4) whether Securities Act Plaintiffs adequately pleaded a claim against “statutory sellers” under Section 12(a)(2); and (5) whether Plaintiffs have adequately pleaded primary Exchange Act and Securities Act claims such that their “control person” claims under Section 20(a) of the Exchange Act and Section 15 of the Securities Act survive Defendants’ Motion.

The parties have extensively briefed the matter, and the Court held oral argument on Defendants’ Motion. For the reasons that follow, the Court grants Defendants’ motion because Plaintiffs have failed to plead material misstatements that trigger liability under Section 10(b) and Rule 10b-5 of the Exchange Act with particularity. Furthermore, the Court finds that Securities Act Plaintiffs’ Section 11 claim sounds in fraud despite its disclaimers to the contrary, and thus, Securities Act Plaintiffs failed to plead those claims with particularity as required by Rule 9(b). The Court finds that Securities Act Plaintiffs adequately alleged that Sotera, Securities Act Selling Shareholders, and Underwriter Defendants are “statutory sellers” under Section 12(a)(2) of the Securities Act, but that Securities Act Plaintiffs failed to adequately allege any actionable untrue statement of material fact or omission in the Initial Public Offering (“IPO”) and Secondary Public Offering (“SPO”) Materials. Having failed to plead a primary Exchange Act or Securities Act violation, Plaintiffs’ derivative “control person” claims under Section 20(a) of the Exchange Act and Section 15 of the Securities Act must also be dismissed.

I. FACTUAL BACKGROUND

A. The Parties

1. The Exchange Act Parties

Lead Plaintiffs are Oakland County Employees’ Retirement System and Oakland County Voluntary Employee’ Beneficiary Association, which are governmental employee benefit plans in

Oakland and Wayne Counties in Michigan that manage approximately \$1.5 billion in assets. (ECF No. 24, Compl., PageID #447–48) (hereinafter “Exchange Act Plaintiffs”). The Exchange Act Plaintiffs purchased Sotera common stock during the Class Period. (*Id.*). The Exchange Act Plaintiffs, along with Plaintiff Wayne County Employees’ Retirement System (collectively, the “Michigan Funds”), serve as lead plaintiffs in this action. (ECF No. 9).

Defendant Sotera Health Company is a Delaware corporation, with a principal place of business in Broadview Heights, Ohio. (*Id.* at PageID #448). Sotera is a global provider of sterilization solutions through its subsidiary, Sterigenics. (*Id.* at PageID #453). Sterigenics is a commercial terminal sterilizer, sterilizing end-use, packaged medical products with EO gas. (*Id.* at PageID #439).

Three of its current or former executives are also named as defendants: Michael Petras, Sotera’s chair and CEO; Scott Leffler, Sotera’s CFO and Treasurer from April 2017 until July 20, 2022; and Kathleen Hoffman, Sotera’s Senior Vice President of Global Environmental, Health and Safety. (*Id.* at PageID# 448) (hereinafter “Exchange Act Officer Defendants”). Exchange Act Plaintiffs allege that Exchange Act Officer Defendants had the power to control the information that flowed to Sotera’s investors, which Exchange Act Plaintiffs aver was materially false and/or misleading. (*Id.* at PageID #449). Exchange Act Officer Defendants purportedly had information that factually contradicted that which they provided to investors, concealing the truth about the dangers and liability risks associated with its EO sterilization operations. (*Id.*).

Also named as defendants in the Exchange Act claims are the “Selling Shareholder Defendants.” These include Defendants Warburg Pincus and GTCR; both of which are private equity firms based out of New York and Chicago, respectively. Both firms were affiliated with investment funds that sold Sotera common stock offered in the SPO, and held 70% of Sotera’s

common stock following the IPO, falling to 62% following the SPO. These entities controlled Sotera throughout the Class Period by virtue of their majority stock holdings, the directors they had power to designate, the directors they placed on the board, the insider knowledge they possessed, and their respective shareholder agreements with Sotera. (*Id.* at PageID #449–50).

Additional “Selling Shareholder Defendants” include the following directors of Sotera: Sean Cunningham, David Donnini, and Constantine Mihas, who were also managing directors at GTCR; and Ruoxi Chen, Stephanie Geveda¹, and James Neary were also managing directors at Warburg (collectively “Exchange Act Selling Shareholder Defendants”). (*Id.* at PageID #449–52). Exchange Act Selling Shareholder Defendants are alleged to have reviewed the IPO Registration Statement, the SPO Registration Statement, and the 2020 and 2021 Form 10-K Statements, and signed them, either themselves or through Petras as attorney-in-fact. (*Id.*).

2. *The Securities Act Parties*

Securities Act Plaintiffs include the Exchange Act Plaintiffs, along with the City of North Miami Beach General Employee’s Retirement Plan and City of North Miami Beach Police Officer & Firefighter’ Retirement Plan (the “North Miami Beach Plaintiffs”) (collectively, the “Securities Act Plaintiffs”). Securities Act Plaintiffs are public pension plans that purchased Sotera common stock during the class period. (*Id.* at PageID #598). The North Miami Beach Plaintiffs each manage over \$100 million in assets, and each bought Sotera common stock pursuant to the IPO and SPO during the class period. (*Id.*; *id.* at PageID #622).

Defendants include Sotera, Petras, and Leffler (Petras and Leffler together are referred to as “Securities Act Officer Defendants”). (*Id.* at PageID #598–99). Defendants Chen, Cunningham, Donnini, Geveda, Mihas, and Neary are named as Sotera’s directors in the same

¹ Defendant Geveda was a director of Sotera from October 2020 until October 2022. (*Id.* at PageID #451; 600).

capacity as they are named in the Exchange Act claims. Directors Ann Klee and Vincent Petrella are also added; like the other named directors, these directors reviewed the IPO and SPO Registration Statements and either signed or authorized Petras to sign those Registration Statements on their behalf (collectively “Securities Act Director Defendants”). (*Id.* at PageID #599–601). Defendants GTCR and Warburg are also similarly named (collectively “Securities Act Selling Shareholders”). (*Id.* at PageID #602–03).

Defendants J.P. Morgan, Credit Suisse, Goldman Sachs, Jefferies, Barclays Capital, Citigroup Global, and RBC Capital Markets served as underwriters and joint lead booking-running managers of the IPO and SPO. (*Id.* at PageID #603–05). Defendants KeyBanc Capital, Citizens Capital, ING Financial, Academy Securities, Loop Capital, Penserra Securities, Siebert Williams, and Tigress Financial served as underwriters and co-managers for the IPO and SPO (collectively “Underwriter Defendants”). (*Id.* at PageID #603–07). The Securities Act Plaintiffs allege that the Underwriter Defendants were responsible for ensuring the truthfulness and accuracy of the statements contained in (or incorporated by reference into) the IPO and SPO Offering Materials. (*Id.*).

B. The Class Period

The Complaint sets forth the Class Period. “The Class Period begins with Sotera’s IPO on November 19, 2020 and ends on September 19, 2022, inclusive, when information from the *Kamuda* verdict alerted investors to the truth about Sotera’s EtO operations.” (ECF No. 24, PageID #440).

C. Sotera’s Business and its EO Gas Emissions

Sotera operates in the healthcare and pharmaceutical industries. (*Id.* at PageID #453). Its primary revenue source is Sterigenics, which provides medical device sterilization services. (*Id.*).

One of Sterigenics's methods for sterilizing medical devices involves the use of EO gas. (*Id.* at PageID #458). Sterigenics's Willowbrook, Illinois facility ("Willowbrook") was shut down in 2019; however, it continues to conduct EO processing in three California facilities, including one in Ontario, California. Other facilities are located in Smyrna and Atlanta, Georgia, Santa Teresa, New Mexico, North Carolina, New York, and Texas. (*Id.* at PageID #458).

Plaintiffs allege that Sterigenics's EO use is irresponsible; they allege that these facilities are in residential areas near schools. (*Id.* at PageID #459). They assert that the vacuum chambers in which to-be-sterilized items are placed contain an unsealed, six-inch fan (a "back vent") through which EO can and does flow to other parts of the facility and is eventually released without mitigation directly into the atmosphere. (*Id.* at PageID #460). They also allege that the post-sterilization phase, during which the sterilized products continued to emit EO gas, also transfers EO directly from the facility into the atmosphere, again without any mitigation by Sterigenics. Sterigenics allegedly released other EO emissions intentionally by leaving shipping and receiving docks open to air out the facilities. (*Id.* at PageID #461). According to Plaintiffs, Sotera and the Selling Shareholders' lobbying efforts—such as successfully lobbying the Illinois EPA ("IEPA") to remove back vent emission controls—demonstrate their knowledge of the risks associated with EO. (*Id.* at PageID #461–62).

D. The *Kamuda* Verdict, Other Litigation, and Regulatory Actions

The United States Environmental Protection Agency ("EPA") classified EO gas as a chemical carcinogen in humans in 2016. (*Id.* at PageID #440). In August 2018, the National Air Toxics Assessment ("NATA") reported that towns near Sterigenics' facilities in Willowbrook, Atlanta, and Santa Teresa were among the highest cancer rates in the country. (*Id.*). Hundreds of lawsuits were then filed against Sotera relating to its emission of EO gas from these facilities.

(ECF No. 24, PageID #462). Plaintiffs acknowledge that Sotera's first Form 10-K after the IPO referenced these lawsuits, which included personal injury cases alleging toxic exposure to EO gas from Willowbrook and Atlanta facilities; employee lawsuits alleging toxic exposure to EO gas; a property-damage lawsuit alleging that the Atlanta facility had devalued surrounding real property and caused other damage; and a lawsuit brought by the New Mexico Attorney General's Office against Sotera, claiming that EO emissions from the Santa Teresa facility constitute a public nuisance and caused significant health risks in the surrounding area. (*Id.*). Plaintiffs allege that, in spite of these actions, Sotera's directors told investors that Sotera was confident it did not generate enough EO gas to cause cancer and would successfully defend the lawsuits. (*Id.* at PageID #463). Plaintiffs also note that documents filed in other litigation in February 2019 alleged that the EO "storage containers at the Willowbrook facility are fully compliant with every applicable law and regulation." (*Id.*).

The Complaint cites *Kamuda v. Sterigenics U.S., LLC*, No. 18 L 10475 (Ill. Cir. Ct. Sept. 26, 2018) as the case that exposed Sotera's irresponsible and harmful EO emissions previously unknown to investors. There, a jury found that exposure to EO caused Ms. Kamuda's cancer. (*Id.* at PageID #440). The *Kamuda* jury awarded Ms. Kamuda \$38 million in compensatory damages and \$325 million in punitive damages, finding that Sotera willfully and wantonly caused Ms. Kamuda's cancer by leaking EO from the Willowbrook facility. (*Id.*; *Kamuda*, No. 18 L 10475 (Sept. 19, 2022)). Sotera appealed the jury verdict and later settled with Ms. Kamuda and other plaintiffs whose cases had been consolidated therewith for a total of \$408 million. (*Id.* at PageID #563; ECF No. 31-1, Mem. in Support of Mot. to Dismiss, PageID #697). The Complaint cites heavily to news articles and other media condemning Sotera for its irresponsible EO usage following the *Kamuda* verdict. (*Id.* at PageID #558–64).

In the same court, Sotera obtained a defense verdict two months later, in another case charging Sterigenics with causing cancer. *Fornek v. Sterigenics*, No. 2018 L 010744 (Ill. Cir. Ct. Nov. 18, 2022) (filed Oct. 4, 2018). (ECF No. 31-1, PageID #690; ECF No. 31-9, PageID #1349–50). Neither the Complaint nor Plaintiffs’ opposition to Defendants’ Motion to Dismiss acknowledges the *Fornek* verdict. The Complaint *does* acknowledge a criminal prosecution related to Sterigenics’s Holland facility and alleges that such matter “Put Sotera On Notice Of Sterigenics’ Pattern Of Ineffective EtO Emissions Controls,” (ECF No. 24, PageID #571); but the Complaint *does not* acknowledge that Sotera’s Holland facility and two individuals “received favorable judgments from the trial court, which did not hold any of them responsible for the alleged criminal offenses.” (ECF No. 31-1, PageID #711; ECF No. 31-5, Form 10-K (fiscal year ending Dec. 31, 2021), PageID #1208). The Complaint also claims that “The New Mexico Attorney General’s Lawsuit Against Sotera Put The Company’s Executives On Notice Of Its Release Of Toxic EtO Emissions.” (ECF No. 24, PageID #572). The New Mexico AG matter remains pending; Sotera is subject to a preliminary injunction in that case that did not require the Santa Teresa facility’s closure, but does forbid Sterigenics “from allowing any uncontrolled emission or release of EO from the facility.” (ECF No. 31-5, PageID #1272).

Plaintiffs claim that various government agencies notified Sotera and its subsidiaries of its failures to effectively control EO emissions. In 2004, the U.S. Chemical Safety and Hazard Investigation Board issued safety recommendations relating to Sotera’s Ontario, California sterilization facility, following an EO-caused explosion that injured four employees. (ECF No. 24, PageID #573). The Court notes that, pursuant to the link contained in the Complaint, such

investigation was closed in 2006, noting “acceptable action” on the part of Sotera.² In 2006, the Occupational Safety and Health Administration (“OSHA”) fined Sterigenics for eight violations related to the “process safety management of highly hazardous chemicals” at the no-longer-operational Willowbrook facility. (*Id.* at PageID #573). There were no noted “failures to abate” nor “willful” violations, and Plaintiffs cite no other recent agency actions relating to Willowbrook.³

Plaintiffs also cite to the South Coast Air Quality Management District’s (“South Coast AQMD”) Notice of Violation to Sterigenics in 2022 for emitting levels of EO at its Vernon, California facility associated with “injury, detriment, nuisance, or annoyance . . . which endanger[s] the comfort, repose, health, or safety of any such persons or the public.” (*Id.* at PageID #575). Plaintiffs claim that the South Coast AQMD issued additional Notices of Violation to Sterigenics relating to the Ontario, California facility in January, April, June, and October of 2022, and most notably in April 2023, when Sterigenics was ordered to close the Ontario facility. (*Id.*).

E. Former Employee Statements

The Complaint includes statements from five anonymous former employees and one named former employee, alleging widespread EO-related safety issues at Sotera’s Sterigenics

² U.S. Chemical Safety and Hazard Investigation Board, *Recommendation No. 2004-11-I-CA-7* (Mar. 30, 2006), <https://perma.cc/3QJA-QGBH>. (See ECF No. 24, PageID #573 n.19, which links to the agency findings and outcome noted above).

³ U.S. Department of Labor, Occupational Safety and Health Administration, *Violation Detail 19100119 D03 II* (Closed Feb. 22, 2006), https://www.osha.gov/ords/imis/establishment.inspection_detail?id=308153717 (see ECF No. 24, PageID #573 n.20, which links to the agency findings and outcomes noted above).

facilities. (*Id.* at PageID #481–87).⁴ First, FE2 worked in Sterigenics’s Smyrna, Georgia facility from January 2018 to January 2019 as an EO Operator. (*Id.* at PageID #481). FE2 moved products in an out of EO sterilization chambers with a forklift. (*Id.*). FE2 claims that he observed employees not wearing appropriate protective equipment and pushing sterilized loads through hallways before they had been “off-gassed” in a controlled environment. (*Id.*). FE2 also claims that the vacuum chambers were not monitored properly or safely maintained; at one point, a spark ignited EO gas and blew a forklift operator out of the chamber, causing the forklift operator to sustain serious injuries. (*Id.*). FE2 states that the EO gas responsible for the explosion had not been detected by existing monitoring systems. (*Id.*). Due to the disrepair of parts in some of Sterigenics’s vacuum chambers, the chambers tended to overheat, causing employees to ventilate the facility by opening garage doors, leaking EO gas into the atmosphere. (*Id.* at PageID #482).

FE3 worked at Sterigenics’s Santa Teresa facility from October 2008 to February 2012 as a shipping clerk. (*Id.*). FE3’s job required him to load trucks with sterilized medical products both before and after they had been completely aerated. (*Id.*). FE3 blames the excessive heat inside the Santa Teresa facility on a broken air conditioner; like the Smyrna facility, employees opened the doors on the shipping dock to ventilate the facility, leaking EO gas into the atmosphere. (*Id.*). Even with the shipping dock doors closed, the doors did not seal, allowing EO gas to leak

⁴ The Complaint also includes statements purportedly made by former employees on the website “glassdoor.com,” along with a CBS News article that quotes former Sterigenics employees. (ECF No. 24, PageID #487–89). Given that websites like “glassdoor.com” allow anyone to post a review to any company (regardless of whether the reviewer actually worked for the company), the Court heavily discounts these statements and does not include them in its analysis, particularly when more specific statements are available from the anonymous and named former employees. The Court likewise discounts and will not consider the CBS News article for the same reasons. *Cf. Ryan v. FIGS, Inc.*, No. 2024 WL 187001, at *13 (C.D. Cal. Jan. 17, 2024) (crediting statements from “glassdoor.com” as confidential witness statements but discounting them because the plaintiffs did not “allege facts supporting an inference that these third-party internet postings, reviews, and articles are reliable and possess knowledge of FIGS’ alleged fraudulent misconduct.”). Even if this Court were to credit the “glassdoor.com” postings and CBS News report that follows, Plaintiffs likewise do not allege any facts supporting the reliability of the postings and the employee statements in the report.

through the cracks into the surrounding air. (*Id.* at PageID #483). FE3 claims that, during his tenure at Sterigenics, employees wore masks for safety, but were not given guidance regarding EO contact with their skin. (*Id.*). FE3 also complained that sterilized products still containing EO gas would often fall off conveyor belts, requiring FE3 to pick them up and place them back on the conveyors. (*Id.*).

FE4 worked at Sterigenics's Santa Teresa facility from 2016 to 2017 as a maintenance technician. (*Id.*). FE4 claims that management actively prevented him from doing things "the right way," claiming, "we don't do that here." (*Id.*). FE4 also claims that facility doors were left open due to the broken air conditioner, allowing EO to escape the facility. (*Id.* at PageID #483–84). FE4 mentions the broken valves in the vacuum chambers, claiming that he asked a supervisor to replace them and received backlash. (*Id.* at PageID #484). When the bulbs necessary for the proper function of the facility's EO "warning lights" went out, they were sometimes not replaced for "two to three days, or sometimes a week." (*Id.*).

FE5 worked in Sterigenics's Atlanta facility from October 2010 to July 2015 as an operator, which is someone who used a computer to start sterilization cycles. (*Id.*). FE5 also loaded and unloaded products from the sterilization chambers and into the aeration room. (*Id.*). FE5 claims that garage doors and other doors were often left open to ventilate the facility, allowing EO gas to escape. (*Id.*). FE5 claims that EO leaks inside and outside the facility were common, including from the chambers and aeration rooms. (*Id.*). Some of the chambers were old, requiring a lot of maintenance. (*Id.* at PageID #484–85). FE5 states that workers were underpaid and the facility was chronically understaffed, causing mistakes related to employee exhaustion. (*Id.* at PageID #485).

FE6 worked in Sterigenics's Ontario, California facility from February 2006 to June 2015 as an EO operator. (*Id.*). FE6 was eventually promoted to lead operator and responsible for running the sterilization cycles. (*Id.*). FE6 claims that the chambers used in Ontario were the same as those used during the 2004 explosion at that facility, though he does not explain how he or she would know this, given his start date two years later. Nonetheless, FE6 alleges that the chambers had been repaired, but the doors and gaskets attached thereto still required frequent maintenance. (*Id.*). FE6 states that the rolling back door near one of the EO chambers was left open daily to ventilate the facility. (*Id.* at PageID #486).

David Marsh worked as Sterigenic's corporate maintenance engineer in June 2012 for an undisclosed duration. (*Id.*). During testimony given to the EPA on May 2, 2023, he claimed that Sterigenics gave him "cancer maps" in 2012 and told him to audit facilities to determine "what kind of stuff [Sterigenics was] leaking, if we are or what we are being blamed for leaking." (*Id.*). Marsh inspected several facilities, including Willowbrook, Smyrna, and Santa Teresa and attempted to fix leaks. (*Id.*). Marsh contracted leukemia, allegedly because of this task; after Marsh's diagnosis, Sotera terminated him. (*Id.*).

F. The IPO

Sotera's Registration Statement was declared effective by the SEC after the markets closed on November 19, 2020; the purported Class Period begins November 20, 2020. (ECF No. 24, PageID #498). On November 23, 2020, Sotera filed its final prospectus for the IPO, which became a part of the company's IPO Offering Materials. (*Id.* at PageID #499). Sotera offered and sold 53.59 million shares of common stock (which included the underwriters' exercise in full of their option to purchase an additional 6.99 million shares of common stock) at \$23.00 per share. (*Id.* at PageID #499).

All parties rely on the IPO Prospectus. For Plaintiffs, the IPO Prospectus represents a series of materially false and misleading statements. For example, Plaintiffs point to Sotera's statement that it

establish[es] reserves for specific liabilities in connection with regulatory and legal actions that we determine to be probable, and reasonably estimable. . . . While it is not possible to determine the ultimate disposition of each of these matters, we do not expect that the ultimate resolution of pending regulatory and legal matters in future periods, including the matters described below, will have a material effect on our financial condition or results of operations. . . . We have not provided for a contingency reserve in connection with these claims. While we intend to vigorously defend the Willowbrook proceedings, there can be no assurance that we will be successful.

(*Id.* at PageID #499). Plaintiffs argue that this statement was materially false and misleading because it does not explain the true extent of Sotera's litigation risks, the inadequacy of its EO emissions control systems, and Defendants' knowledge thereof. (*Id.* at PageID #499–500).

Plaintiffs also claim that Sotera downplayed the liability risk it faced from “lawsuits alleging that purported EO emissions from certain of [Sotera's] current and former facilities have resulted in toxicological or health-related impact on the environment, the communities that surround [Sotera's] facility and a customer[’s] employees,” repeatedly stating that “[w]e deny these allegations and are vigorously defending against these claims.” (*Id.* at PageID #500) (clarification in original, emphasis in original removed). Plaintiffs claim that Sotera's denial of the allegations were materially false and misleading and/or omitted material facts because Sotera was aware of the carcinogenic properties of EO, but chose not to employ adequate and effective EO emissions controls and allowed EO to escape the facility unabated. (*Id.*)⁵

⁵ The Securities Act Plaintiffs rely on additional statements in the IPO Prospectus that they allege were false and/or misleading. Since those statements are only relevant to the Securities Act claims, they are described and discussed in the portion of this Order addressing those claims.

Defendants point to other statements in the IPO Prospectus. Defendants note that the IPO Prospectus acknowledged that Sotera was both “subject to environmental, health and safety laws and regulations in the jurisdictions in which we operate, including laws, regulations and permit requirements with respect to” EO; and that “[w]hile we strive to comply with these regulatory requirements, we may not at all times be in full compliance and, as a result, could be subject to significant civil and criminal fines and penalties.” (ECF No. 31-1, PageID #688). The IPO Prospectus likewise warned that “[p]otential health risks associated with exposure to EO under certain conditions subject us to the risk of liability claims being made against us by workers, contractors, and others, including individuals who reside or have resided near our EO sterilization facilities and employees or our customers.” (*Id.*). Sotera warned that these risks are evolving over time; as years have passed, the EPA identified EO gas as a potential cancer concern and specifically identified the areas around Sotera’s Willowbrook, Atlanta, and New Mexico facilities as having particularized cancer concerns. (*Id.* at PageID #688–89). In light of this evolution, the IPO Prospectus states that Sotera could “give no assurances” that these assessments would not impact its “business, prospects, financial condition or results of operations.” (*Id.* at PageID #689).

Upon review, the IPO Prospectus contains a number of noteworthy disclosures. For example, the IPO Prospectus begins on page one with: “**Investing in our common stock involves a high degree of risk. See “Risk Factors” beginning on page 22 to read about factors you should consider before deciding to invest in our common stock.**” (ECF No. 31-3, IPO Prospectus, PageID #724). Those risk factors include headings such as:

- “*Changes in environmental, health and safety regulations and preferences may negatively impact our business*” (*id.* at PageID #749);

- *“Safety risks associated with the use and disposal of potentially hazardous materials, such as EO and Co-60, may result in accidents or liabilities that materially affect our results of operations” (id. at PageID #750);*
- *“Potential health risks associated with the use of EO may subject us to future liability claims and other adverse effects” (id. at PageID #751);*
- *“We are currently defending certain litigation, and we are likely to be subject to additional litigation in the future” (id. at PageID #752);*
- *“We are subject to extensive regulatory requirements and routine regulatory audits in our operations. We must receive permits, licenses and/or regulatory clearance or approval for our operations. Compliance with these regulations is costly, and failure to comply with all laws and regulations or to receive or maintain permits, licenses, clearances or approvals may hurt our revenues, profitability, financial condition or value” (id. at PageID #755);*
- *“We have a history of net losses and may not achieve or maintain profitability in the future” (id. at PageID #764); and*
- *“The market and trading volume of our common stock may be volatile, and you could lose all or part of your investment” (id. at PageID #770).*

These sections disclose that EO is both flammable and explosive, and state:

Any incident occurring at any of our EO or gamma facilities that causes harm to workers or others or the interruption of normal operations at the affected facility could result in substantial liability to us. We are currently the subject of lawsuits alleging that purported EO emissions from certain of our current and former facilities have resulted in toxicological or health related impact on the environment, the communities that surround our facility and a customer’s employees. We deny these allegations and intend to vigorously defend against these claims. We have also from time to time been involved with workers’ compensation claims relating to potentially hazardous materials. We may be subject to similar claims in the future, and

one or more adverse judgments could result in significant liability for us and have a material adverse effect on our business, financial condition and results of operations.

(*Id.* at PageID #750). Regarding pending litigation, the IPO goes on to warn:

We are currently the subject of tort lawsuits alleging personal injury by purported exposure to emissions and releases of EO from our facility in Willowbrook and our facility in Atlanta. Additionally, we are defendants in a lawsuit by certain employees of a contract sterilization customer in Georgia who allege personal injury by workplace exposure to EO. We are also defendants in a lawsuit alleging that our Atlanta facility has devalued and harmed the plaintiffs' use of a real property they own in Smyrna, Georgia and additional property devaluation claims have been threatened. We deny the allegations and are vigorously defending these claims. . . . It is likely that we will be subject to other claims by similar groups of plaintiffs in the future relating to any of our current or former facilities. In addition, we have encountered and will likely continue to encounter resistance, protests or other actions in communities where our existing facilities are located or where we seek to establish or expand facilities based on the perceptions of the risk associated with exposure to EO held by some residents and officials of these communities. This publicity may also have other adverse impacts, including damage to our reputation and public pressure against our facilities that may affect our ability to conduct our business.

Our liability insurance coverage may not be adequate to cover any liabilities arising out of such allegations or remain available to us at acceptable costs. A successful claim brought against us in excess of the insurance coverage then available to us could have a material adverse effect on our business, prospects, financial condition or results of operations.

...

Our business exposes us to significant potential risk from lawsuits, investigations and other legal proceedings. We are currently pursuing and defending various proceedings and will likely be subject to additional proceedings in the future, including potential litigation regarding the products and services we provide[.]

...

... [O]ne or more adverse judgments could result in significant liability for us and have a material adverse effect on our business, financial condition and results of operation. In addition, we have been involved in litigation in Georgia against local officials to allow us to resume operations at our

Atlanta facility that have been suspended while we installed enhancements to our EO emissions control systems, as well as to challenge local officials' unsupported claims of loss of neighboring residential property values in tax assessments.

...

... In some instances, even if we comply with applicable laws and regulations, including those relating to emission standards, an adverse judgment or outcome may occur based on the other applicable laws or principles of common law, including negligence and strict liability, and result in significant liability and reputational damage for us. It is likely that we will be subject to other claims in addition to those described above by similar groups of plaintiffs in the future relating to any of our current or former facilities or activities. In addition, awards against and settlements by our competitors or publicity associated with our current litigation could incentivize parties to bring additional claims against us.

Any claim brought against us, regardless of its merits, could be costly to defend and could result in an increase of our insurance premiums and exhaust our available insurance coverage. The financial impact of litigation, particularly class action and mass action lawsuits, is difficult to assess or quantify. Some claims brought against us might not be covered by our insurance policies or might exhaust our available insurance coverage for such occurrences. Furthermore, an insurer might refuse coverage, and even where the claim should be covered by insurance, we have significant self-insured retention amounts, which we would have to pay in full before obtaining any insurance proceeds. To the extent our insurance coverage is inadequate and we are not successful in identifying or purchasing additional coverage for such claims, we would have to pay the amount of any settlement or judgment that is in excess of policy limits. We have reached the per occurrence limit of our insurance coverage for claims related to Willowbrook's EO emissions due to legal costs associated with such claims and have not yet been and likely will not be successful in identifying or purchasing additional coverage for such claims. If any judgments are rendered against us and are upheld on appeal, we would not have insurance coverage to cover such judgment. Claims against us that result in entry of a judgment or we settle that are not covered or not sufficiently covered by insurance policies, or which fall within retained liability under our policies, could have a material adverse impact on our business, prospects, financial condition or results of operations.

...

Further, government action may disrupt the operations of our facilities that process potentially hazardous materials. For example, in February 2019 the

Illinois Environmental Protection Agency (“IEPA”) issued a seal order temporarily shutting down our sterilization activities at our Willowbrook facility, and in October 2019, county officials ordered our Atlanta facility, the operations of which had been voluntarily suspended at the time, remain closed until county approval is obtained. Although our Atlanta facility was allowed to resume operations under a Temporary Restraining Order imposed on county officials in April 2020, our facility could be forced to close again upon the resolution of related litigation. The occurrence of any of these or other events might disrupt or shut down operations or otherwise adversely impact the production of profitability of a particular facility or our operations as a whole.

(*Id.* at PageID #752–53). Lengthy descriptions of various legal proceedings, including a regulatory action brought by the Illinois Attorney General; tort litigation in Illinois that included *Fornek*, *Kamuda*, the class action with which it was consolidated, a subsequent class action in Illinois; the Georgia action brought by a customer’s employees; the Georgia action concerning declining property values leading to lower tax assessments; the additional real-estate related actions in Georgia; litigation related to the suspension of the Georgia facility; and the Holland criminal proceeding are likewise included. (*Id.* at PageID #845–49).

Regarding regulatory compliance, the IPO Prospective states, “While we strive to comply with these regulatory requirements, we have not always been and may not always be in compliance and, as a result, can be subject to significant civil and criminal fines and penalties, including the shutdown of our operations or the suspension of our licenses, permits or registrations.” (*Id.* at PageID #756). Among the factors that may cause volatility in Sotera’s common stock, the IPO Prospectus lists “developments in our litigation matters and governmental investigations or additional significant lawsuits or governmental investigations relating to our services or facilities;” and “adverse publicity about us or the industries in which we participate.” (*Id.* at PageID #770).

G. The SPO

The SPO became effective on March 18, 2021, with the filing of its SPO Registration Statement and Prospectus. (*Id.* at PageID #511). These documents contained identical statements to those referenced in the IPO Prospectus regarding liability risk, safety, and emissions control systems. (*Id.*).

H. Sotera's Subsequent Statements Regarding Permit and Regulatory Compliance, EO Litigation, and EO-Related Health and Safety

Plaintiffs identify numerous statements made by Sotera, Exchange Act Officer Defendants, and Exchange Act Selling Shareholders between the SPO and the *Kamuda* verdict that materially misled investors. Many of these statements are replicated on Sotera's Investor Web Portal but are not included in this Order because they are generally duplicative of the statements cited at length. (*Id.* at PageID #540–52). While Plaintiffs' recitation of these alleged misstatements spans more than 50 pages of their Complaint, the Court can categorize these statements as addressing (1) permit and regulatory noncompliance; (2) pending litigation; and (3) EO-emissions and health-and-safety initiatives. Regarding many of the statements, the Complaint recites:

These statements were materially false and misleading when made and/or omitted material information because in truth, (i) Sotera chose not to employ adequate and effective EtO emissions control systems at its sterilization facilities; and (ii) Sotera often subverted whatever control systems the Company did have, allowing dangerous amounts of toxic EtO fumes to pollute the air surrounding those facilities and exposing people living in the adjacent communities to significantly increased cancer risks.

(ECF No. 24, PageID #503–04; 510; 513; 517–18; 522–23; 527; 530–32; 536–37; 539; 541–43; 545; 551; *see id.* at PageID # 507–08; 512; 514; 516; 525–26; 528; 533; 534; 538; 546–50 (making identical allegations without labeling them (i) or (ii)). Any additional bases for Plaintiffs' allegation that these statements are materially false and misleading are cited following each statement category.

1. Permit and Regulatory Compliance

First, Sotera and its executives are alleged to have made the following false and/or misleading statements with regard to their permits and regulatory compliance:

- At the January 11, 2021 J.P. Morgan 39th Annual Healthcare Virtual Conference, in response to a question about the New Mexico Attorney General litigation, Petras expressed dismay at the suit, and then stated, “They have asked for improvements to the process of what’s occurring in that facility and sterilization process. And as I’ve told many of our investors, we are aggressively pursuing facility enhancements across all of our EO facilities in the United States. . . . We continue to comply with all permits.” (*Id.* at PageID #502; *see id.* at PageID #542 (quoting the Sotera Web Portal, “Sterigenics consistently complies with environmental permits issued for each of its sterilization facilities”)). Petras also expressed a desire to take care of Sotera’s customers, employees, surrounding communities, and the patients who receive sterile products. (*Id.*). Regarding revised EPA guidelines related to EO, Petras stated:

Yes. So we are anxiously awaiting new regulations. We have said since 2018 just give us the rules and we will play and abide and far exceed any of the expectations from the regulators. We’ve done this for the history of our company and we are waiting for the rules. . . . All I can tell you is that we have put in our enhancements and our facilities, we’re working aggressively to get those rolled out. We put them in Atlanta. And today in Atlanta, we captured 99.99% of the emissions coming out of that facility. But of the EO used, it was 99.99% of the EO used. We’re capturing it to make sure it doesn’t get out in emissions. . . . I feel very confident that what the regulators come out in new regards [*sic*] and new rules and regs are going to be very closely resembling what we’ve done in Atlanta and it will further demonstrate our leadership position in this area. So what we want are the rules. Tell us the rules and we’ll go right now. We’re solving form [*sic*] as best we can without clarity from the government officials on the new NESHAP regulations. I feel we’re well positioned.

- (*Id.*; *see id.* at PageID #509 (citing the capture of 99.99% of emissions from the Georgia facility during a March 9, 2021 earnings call, stating that Sotera anticipated its improvements would be “the key benchmarks and baselines that NESHAP uses for their longer-term regs, but we don’t know that until we see it come out”); *id.* at PageID #517 (calling the Georgia emissions capture “the gold standard for the industry in terms of taking [an] innovative approach to emission control and rolling it out with a very high level of efficacy in terms of the performance there”) (clarification added); *id.* at PageID #518 (suggesting that emissions escape following 99.9999% capture are unlikely to cause cancer in a person)).
- At the February 24, 2021 Citi 2021 Healthcare Services, Medtech Tools, & HCIT Virtual Conference, Leffler informed those in attendance that Sotera has “a high degree of confidence in our ability to comply with any regulatory requirement. We have a successful record of doing that for many decades, [and] . . . we’ve proven over the years our ability to comply with any new regulatory requirements. We believe that we’re an industry leader and have a competitive advantage in that area.” (*Id.* at PageID #503; *see id.* at PageID #524 (quoting Leffler from his appearance at the November 11, 2021 Credit Suisse 30th Annual Healthcare Conference, at which Leffler stated, “we have[,] we believe a competitive advantage when it comes to understanding and complying with complex and burdensome regulations”) (clarification added); *id.* at PageID #531 (quoting Leffler’s statements at the March 22, 2022 Keybank Capital Markets Life Sciences & MedTech Forum, stating, “we’ve always said that we feel that we have a competitive advantage when it comes to understanding and complying with complex regulations”); *id.* at PageID #535 (quoting Leffler’s statements at the May 17, 2022

RBC Capital Markets Healthcare Conference, stating, “We’re making significant investments in our own infrastructure in order to ensure that we are at the forefront of deploying the best technology that’s available as far as emission control system[s] so that when the new regulations come out, we’re better positioned than anybody to actually do even better in that environment because we believe that the capabilities we have when it comes to complying with complex and burdensome regulations are actually one of our competitive differentiators”) (clarification added); *id.* at PageID #542 (quoting Sotera’s Investor Web Portal, “[Sotera] has a track record of implementing leading safety practices to further perform better than regulatory requirements”)).

- At the March 23, 2021 KeyBanc Life Sciences & Medtech Investor Forum, Leffler stated that, given Sotera’s (combined with its predecessors’) lengthy experience using EO for sterilization purposes, “we have always been very comfortable in our ability to understand and comply with the regulatory environment. And we’re very proud of our track record of compliance.” (*Id.* at PageID #513). Leffler went on to state that Sotera has voluntarily published emissions data “because we’ve been so proud of our ability to go above and beyond the – better than the regulatory requirements in terms of emission control.” (*Id.*; *see id.* at PageID #541 (quoting Sotera’s Investor Web Portal, which states, “Sterigenics has a track record of continuous improvement with control systems that go beyond regulatory requirements for EO emissions. Sterigenics is committed to best-in-class emission controls and is working with communities and regulators to establish the strongest possible control environment across its network of EO sterilization facilities”); *id.* at PageID #541 (quoting similar statements appearing

on Sotera's Investor Web Portal, which explain that EO sterilization is heavily regulated, and that Sotera operates safely and does "far better than environmental standards").

- During the August 12, 2021 Q2 2021 earnings call, Petras was asked about state efforts to increase regulation of EO; in response, Petras stated, "As far as new regs and new restrictions being put on by other facilities around the country, we're not seeing that. . . . We work with regulators on an ongoing basis, and we continue to operate in those facilities. . . . I can't predict some of the irrational activity that's happened in the past. What that means for forward, but what I can tell you is, we're in compliance with our permits and the regs." (*Id.* at PageID #521).

Plaintiffs allege that it was false and misleading to claim that Sotera would "continue to comply with all permits" when over the life of the Willowbrook facility, Sotera failed to comply with permits designed to limit and monitor EO emissions. (*Id.* at PageID #503). Plaintiffs further claim that it was false or misleading to state that Sotera had "many decades" of regulatory compliance when, over the 40+ year life of the Willowbrook facility, Sotera failed to comply with multiple permits designed to limit and monitor EO emissions. (*Id.* at PageID #504; 513; 542).

2. *Litigation-Based Statements*

Next, Plaintiffs allege that Defendants made the following false and/or misleading statements during the Class Period with regard to the personal injury, employment, and regulatory litigation in which Sotera was involved:

- In its 2020 Form 10-K (dated March 9, 2021), Sotera referenced numerous litigation-based claims against it and stated, "We deny these allegations and intend to vigorously defend against these claims." (*Id.* at PageID #505–07)

- During a March 9, 2021 earnings call, Petras informed those in attendance that “we feel very comfortable about where we are in [the EO] litigation and the work that our teams are putting together in our defense. Ultimately, though, it’s going to go in front of a trial jury, and there’s risk that come [*sic*] associated with that. . . . We have very compliant systems. It’s built into our culture, and we continue to operate with high regard for the regulatory requirements.” (*Id.* at PageID #509; *see id.* at PageID #539 (quoting Petras during the August 4, 2022 Q2 2022 earnings call, stating, “[T]he company intends to vigorously defend itself against these claims. Our company plays a critical role in healthcare, and our employees and facilities operate in a safe and compliant manner”).
- In Sotera’s Q1 2021 Form 10-Q (dated May 13, 2021), Sotera disclosed details about the *Kamuda* litigation, and again stated that it “denies these allegations and intends to vigorously defend them.” (*Id.* at PageID #515). Sotera also indicated its anticipation of further litigation:

Additional personal injury, property devaluation or other lawsuits may be filed in the future against us or our subsidiaries relating to Sterigenics’ Willowbrook, Atlanta, Santa Teresa or other EO sterilization facilities. The Company, Sterigenics U.S., LLC and other Company subsidiaries intend to defend themselves vigorously in all such current or future EO litigation.

While an adverse outcome in one or more of the proceedings could have a material adverse effect on our business, financial condition and results of operations, no contingency reserve has been reflected in our consolidated financial statements as a loss is not deemed probable, nor is a loss or range of losses reasonably estimable.

We establish reserves for specific liabilities in connection with regulatory and legal actions that we determine to be both probable and reasonably estimable. No material amounts have been accrued in our consolidated financial statements with respect to any loss contingencies. In certain of the matters described below, we are not able to make a reasonable estimate

of any liability because of the uncertainties related to the outcome and/or the amount or range of loss. While it is not possible to determine the ultimate disposition of these matters, we do not expect that the ultimate resolution of pending regulatory and legal matters in future periods, including the matters described below, will have a material effect on our financial condition or results of operations . . .

(*Id.* at PageID #515–16; *see id.* at PageID #534 (quoting Sotera’s May 5, 2022 Q1 2022 Form 10-Q, which contains a statement identical to the last paragraph cited above)).

- At the June 8, 2021 Goldman Sachs 42nd Annual Global Healthcare Virtual Conference, Petras predicted an increase in EO regulation and stated that Sotera has “made a practice for many, many years [*sic*] have continued to get better.” (*Id.* at PageID #517). Petras later stated, “We don’t believe that if we were to lose cases here in this we don’t think it’s a material long-term impact to the company based on the low level of ethylene oxide that’s coming out of these facilities. Remember 1% of all the ethylene oxide use [in the] United States is used with sterilization less than 1%” of EO. (*Id.* at PageID #518).
- Sotera disclosed details of the regulatory litigation filed by the New Mexico Attorney General in its August 12, 2021 Q2 2021 Form 10-Q. (*Id.* at PageID #519). These details included the nature of the suit and details of the preliminary injunction entered there (called “the Order” in the 10-Q). Following entry of the preliminary injunction, Sotera stated, “Sterigenics promptly took steps to monitor its compliance with the Order.” (*Id.*). Sotera also disclosed that it had been working to implement emission control enhancements in Santa Teresa, New Mexico, and received a permit from the New Mexico Environmental Department two months prior, “clearing the way for the next steps in Sterigenics’ implementation of these additional emission control enhancements.” (*Id.* at PageID #520).

- During the September 21, 2021 Virtual JP Morgan 12th Annual U.S. All Stars Conference, Petras was asked about upcoming jury trials, which included *Kamuda* and *Fornek*. (*Id.* at PageID #522). Petras stated:

Listen, we feel very good about our position here. And this is a very low amount of yield. There's no violation of our permits or the laws around EO usage, that's being claimed against us here. People have to show causation. They have to show and demonstrate that this very small amount of EO cause[d] a person's cancer. I don't want you to think we're a callous organization. All of us have had cancer touch our family members in some way, shape or form. . . .

I feel pretty confident and our organization feels confident that these facilities did not generate enough EO to cause cancer in these plaintiffs, okay? That's ultimately, what has got to be proven in the court. . . . We're not settling, we're moving forward here and going forward with the trials. And that's the plan and we think there's a tall task here. There's been no material awards on a chemical[] at this low level, particularly ethylene oxide, where people have got the material win from this. And we don't see that changing here.

(*Id.* at PageID #522–23).

- On March 1, 2022, during the Q4 2021 earnings call, Petras was again asked about the Willowbrook litigation, including *Kamuda* and *Fornek*; Petras responded that Sotera was “anxious to get those done. We've got our teams very focused on our defense and we feel good about where we're positioned today, but ultimately, it can [*sic*] be decided in the courts.” (*Id.* at PageID #530).
- During the March 22, 2022 Keybank Capital Markets Life Sciences & MedTech Forum, Leffler stated that Sotera's continued outlook towards *Kamuda*, *Fornek*, and other litigation stemming from Willowbrook, was positive: “[W]e fundamentally feel that the company's arguments are strong, and we look forward to the opportunity to prove that out in the cases that are upcoming.” (*Id.* at PageID #531).

- Sotera's position regarding litigation remained unchanged during the May 17, 2022 RBC Capital Markets Healthcare Conference, at which Leffler informed those in attendance:

Now, as far as litigation . . . On a backward-looking basis, there are some claims that relate to alleged exposure around particularly our facility in Illinois. We absolutely feel that the company has always been in the right as far as making the appropriate efforts and investments in its operations.
* * *

Obviously, we feel very strongly about the strength of our position, but it is a – each one of these is going to be a jury trial, and it's going to be up to the jury to make the final determination. But again, we feel very strongly about our positions there.

(*Id.* at PageID #535–36).

- At the June 14, 2022 Goldman Sachs 43rd Annual Global Healthcare Conference, Petras informed those in attendance that Sotera “did not cause the cancer” alleged in *Kamuda*, *Fornek*, and other Willowbrook EO litigation. (*Id.* at PageID #537). Petras went on to state:

At the end of the day, it's got to be proven in front of a jury that our facilities cause cancer. And I don't believe that's the case. We firmly believe that we're going to defend it. . . . [I]f we don't get the results we want, there will be an appeal. And I'm sure, if the other side does not get the result they want, there's going to be an appeal. . . . We do not believe it's a material long-term impact to the company. We have a company that's multi-billions of dollars and we operate in a compliant manner, follow the rules and regs, and we feel pretty confident in our position. But again, there's risk, we've got to deal with the courts on this.

(*Id.*). Asked how Sotera gets investors to think about those risks, Petras responded:

We have not obviously booked any reserves or anything, yes, because we don't think there's a high probability we're going to lose and we wouldn't know what to book at this point in time. What I would tell you is, we don't believe it's a material long-term impact to the company.

I would just tell you, believe in our mission, of what we do day-in and day-out. We're going to follow the regulations, be compliant with them. . . . We don't believe it's a material long term impact to this company.

(*Id.*).

Plaintiffs allege that these statements were false and misleading because the evidence presented at the *Kamuda* trial showed Sotera's failure to disclose "the potential significant risk of an adverse outcome at trial." (*Id.* at PageID #508). Plaintiffs claim that Sotera withheld information about its inadequate EO emissions control systems from investors, rendering these statements about pending litigation materially false and misleading. (*Id.* at PageID #516, 520, 522). According to Plaintiffs, since Sotera knew its emissions control systems were leaking EO gas into the air, at times through employee subversion of those systems, it was misleading for Sotera to fail to account for litigation losses and to represent to investors that "a loss is not deemed probable." (*Id.*; *see id.* at PageID #534–35; 538–39 (alleging that this knowledge also rendered misleading Sotera's failure to account for potential litigation losses in the Company's financial statements and to represent to investors that "we do not expect that the ultimate resolution of pending regulatory and legal matters in future periods . . . will have a material effect on our financial condition or results of operations"))).

3. *Health-and-Safety and Emissions-Based Statements*

The third category of false and/or misleading statements Defendants are alleged to have made concern Sotera's commitment to health and safety initiatives and its general statements about EO emissions:

- In Sotera's 2020 Form 10-K (dated March 9, 2021), Sotera told investors that Sotera "drive[s] operational excellence across our network of facilities in order to achieve [a] high level of safety, quality, operating efficiency and customer satisfaction." (*Id.* at PageID #505) (clarification added). Sotera went on to state that it has a "proactive environmental health and safety ("EH&S") program and a culture of safety and quality across all business units," and that, "We consistently meet and outperform regulatory emissions control

requirements, although we have experienced instances of emissions exceeding applicable standards, none of which we believe were material.” (*Id.*). Sotera further explained that it was “investing in additional voluntary controls on EO emissions at our facilities to outperform current and expected future regulatory requirements and further reduce facility emissions.” (*Id.*; *see id.* at PageID #525 (showing that Leffler repeated this claim at the November 11, 2021 Credit Suisse 30th Annual Healthcare Conference: “But in many cases, we’ve gone above and beyond the emission disclosure requirements, and voluntarily disclosed emission information that wasn’t even required under the regulatory regime”); *id.* at PageID #525 (citing the January 11, 2022 Form 8-K Investor Presentation, which stated, “Sterigenics [is] investing in enhanced EO emission controls, well beyond regulatory requirements”). This statement was again qualified by the fact that Sotera has “experienced instances of emissions exceeding applicable standards, none of which we believe were material.” (*Id.* at PageID #506). Lastly, the March 9, 2021 Form 10-K states that Sotera has “made proactive, voluntary investments to enhance emissions controls.” (*Id.* at PageID #506).

- During the March 9, 2021 Q4 2020 earnings call, Petras explained that, following the successful capture of 99.99% of emissions from the Atlanta facility, Sotera had additional plans to improve its other facilities to that same standard: “[W]e’ve always been on the forefront and a leader in operating these facilities and with the emission control systems that have been in place, and we continue to feel confident on where we are. Atlanta is up and running. We’ve already put improvements into another couple of facilities that are near completion and then others that are falling behind in that same path.” (*Id.* at PageID

#509–10; *see id.* at PageID #541 (quoting Sotera’s Investor Web Portal, which stated, “Sterigenics is leading the industry in recent [EO] enhancements”)).

- Plaintiffs take issue with Sotera’s April 15, 2021 Proxy Statement, which states under a heading called “Our Values,” “Safety / We are uncompromising in our commitment to health and well-being. * * * Integrity / We are honest, reliable and accountable in everything we do.” (*Id.* at PageID #514).
- At the January 11, 2022 J.P. Morgan 40th Annual Healthcare Conference, Petras discussed the emissions control improvements and the timeline for implementation, again lauding the Atlanta facility’s performance:

So we’ve got in process many of these facilities and anywhere from design or waiting on approvals or permits, or we’ve got the permits and we’re ramping up construction and renovation efforts. So I could just tell you this will continue at least through 2022 and 2023 and possibly into 2024. It’s just depending on the timing of when regulators want a final approval of these things, and its not that they’re not approving them. It’s just they have other more pressing things that they maybe [*sic*] attending to in their local markets. But we feel good about how this is progressing and we feel really good about the solution we put in Atlanta and some of these other facilities. They’re working really well.

(*Id.* at PageID #527).

- During the March 1, 2022 Q4 2021 earnings call, Petras again mentioned the improvements to the Atlanta facility: “although we’ve had a facility up and operating in Georgia for quite some time with improvements, which again are world leading in many aspects, we are also pleased to see that [is] recognized by the regulators. . . . [W]e’re very encouraged by the things that we’re doing in this area and we’re going to continue to move forward with that strategy.” (*Id.* at PageID #530) (clarification added).
- In Sotera’s April 14, 2022 Proxy Statement, Sotera expressed its commitment to health and safety, citing its mission as “Safeguarding Global Health,” and stating that it strives “to

ensure healthy lives and promote well-being for people around the world.” (*Id.* at PageID #532). The 2022 Proxy Statement offered other information about Sotera’s environmental health-and-safety (“EHS”) initiatives. (*Id.*). Sotera claimed to track both leading and lagging EHS performance metrics, such as safety improvement reporting and timely completion of corrective actions. (*Id.*). Sotera stated that it has “robust EHS Management systems based on the requirements of ISO 14001 (environmental management) and/or ISO 45001 (occupational health and safety) standards.” (*Id.*). Sotera also stated that Sterigenics was actively “investing tens of millions of dollars in emission control enhancements at EO facilities to further reduce emissions beyond already safe levels.” (*Id.* at PageID #533). Sotera further claimed, “Sterigenics has a history of enhancing work practices and emission controls with the aim of reducing EO emissions.” (*Id.* at PageID #533).

- Speaking on the downside for EO facilities in the United States at the June 14, 2022 Goldman Sachs 43rd Annual Global Healthcare Conference, Petras stated that it would be unfortunate if the EPA’s regulations were significantly lesser than those Sotera has been implementing; even so, Petras stated, “. . . to us, it’s the right thing to do. So it doesn’t matter. And we’re going to sell it to our customers. We’re going to tell the industry. We have the most advanced controls in the industry.” (*Id.* at PageID #536).
- On Sotera’s Investor Web Portal, Sotera informed investors that, “No generally accepted science demonstrates that low-level EO exposure from Sterigenics’ facilities cause medical conditions.” (*Id.* at PageID #544). Sotera also provided its investors with independent research through its Web Portal, informing investors, “that the most recent and informative studies on [cancer risks among workers exposed to EO] ‘do not support the conclusion that

exposure to EO is associated with an increased risk of lymphohematopoietic cancers (LHC) or breast cancer””; and that the National Institute of Occupational Safety and Health’s (“NIOSH”) reevaluation of the EPA’s 2016 IRIS risk assessment “suggested that the US EPA’s exclusive reliance on the NIOSH cohort to estimate EO cancer risk should be reexamined.” (*Id.*).

Plaintiffs allege that these statements are false and misleading because “Sotera’s executives and controlling shareholders knew of the significant health risks associated with exposure to elevated levels of EtO”, but “chose not to employ adequate and effective emissions control systems at its sterilization facilities, and often subverted whatever control systems the Company did have, allowing dangerous amounts of toxic EtO fumes to pollute the air surrounding those facilities and exposing people living in the adjacent communities to significantly increased cancer risks.” (*Id.* at PageID #507–08; 526; 533). Plaintiffs claim that, rather than a proactive safety culture, Sotera actively tried to prevent regulators and the public from learning about EO’s true harmfulness. (*Id.*). Plaintiffs again cite to the South Coast AQMD finding, which required Sotera’s Ontario, California facility to temporarily close due to “[e]levated Ethylene Oxide Readings,” in order “to take steps to immediately reduce health risks from its EtO operations.” (*Id.* at PageID #526).

I. Sotera Common Stock Prices Following the SPO

Following the SPO, Sotera stock trended downward, only once rising above its initial baseline, in March 2021. (ECF No. 24, PageID #565, graph). The Complaint observes that, following the *Kamuda* verdict, Sotera’s stock price dropped sharply from \$14.73 per share to \$9.83 per share. (*Id.* at PageID #560, 565, graph). While the graph in the Complaint cuts off at this downward slip, Defendants argue that Sotera’s stock price increased by nearly twenty-five percent following the *Fornek* verdict in Sotera’s favor. (ECF No. 31-1, PageID #690). The publicly

available stock prices attached to Defendants’ Motion to Dismiss bear out this resurgence. (ECF No. 31-8, PageID #1332–33).

J. Procedural History

On May 1, 2023, Plaintiffs filed the Complaint against Defendants, alleging that they made materially false and misleading statements between the IPO and *Kamuda* verdict upon which investors relied, ultimately producing a significantly lower-than-anticipated value of Sotera’s shares. (ECF No. 24). The Complaint asserts six causes of action: (i) violations of Section 10(b) and Rule 10b-5(b) of the Exchange Act against Sotera, Exchange Act Officer Defendants, and Exchange Act Director Defendants, (ii) violations of Section 10(b) and Rule 10b-5(a) and 5(c) of the Exchange Act against Sotera and Officer Defendants, and (iii) violation of Section 20(a) of the Exchange Act against Officer Defendants and Exchange Act Selling Shareholder Defendants; (iv) violations of Section 11 of the Securities Act against Securities Act Defendants and Underwriter Defendants, (v) violation of Section 12(a)(2) of the Securities Act against Sotera, Securities Act Selling Shareholder Defendants, and Underwriter Defendants, and (vi) violations of Section 15 of the Securities Act against Petras, Securities Act Director Defendants, and Securities Act Selling Shareholder Defendants. (*Id.* at PageID #586–94, 617–25).

On August 2, 2023, Defendants moved to dismiss Plaintiffs’ Complaint under Fed. R. Civ. P. 12(b)(6). (ECF No. 31). Defendants allege that the Complaint fails to state a claim upon which relief can be granted because Plaintiffs have not met applicable pleading standards, and relevant Defendants disclosed known, material risks associated with purchasing Sotera’s common stock in the IPO and repeatedly thereafter. They argue that (1) Plaintiffs failed to establish that the statements are materially false and/or misleading; (2) Plaintiffs failed to plead particularized facts to allege scienter; and (3) that the Class Period occurred after the allege “scheme” had concluded.

(ECF No. 31-1, PageID # 690–716). Defendants argue that many of the statements constitute opinions, inherently aspirational statements, and corporate optimism, (*id.* at PageID #703–06), or are protected by either or both of the PSLRA Safe Harbor and the Bespeaks-Caution Doctrine (*id.* at PageID #706–08).

Securities Act Defendants argue that Securities Act Plaintiffs lack standing to bring their Section 12(a)(2) claim because only certain plaintiffs purchased Sotera common stock traceable to the IPO and/or SPO, and there is no allegation of solicitation by the Securities Act Selling Shareholder Defendants. (*Id.* at PageID #716). Absent primary violation of either the Exchange Act or Securities Act, Defendants assert that Plaintiffs’ derivative “control person” claims under Section 20(a) of the Exchange Act and Section 15 of the Securities Act must also be dismissed. (*Id.* at PageID #716).

Plaintiffs oppose Defendants’ Motion. (ECF No. 32). The *Kamuda* jury found that Sotera willfully and wantonly allowed EO gas to pollute Willowbrook, Indiana and impact its residents’ health. (ECF No. 32, PageID #1485). Plaintiffs argue that this verdict shows that Defendants both (1) knew about the dangers of EO for decades, and (2) hid material information from investors and the public in contravention with Sotera’s public statements and disclosure requirements. (*Id.* at PageID #1484–85). Those matters, plus Petras’s sale of his common stock during the IPO and SPO establish the “strong inference” of scienter required to overcome Defendants’ Motion. (*Id.* at PageID #1500–06). Given Sotera’s alleged permit and regulatory violations, Plaintiffs claim that Defendants’ (minus Underwriter Defendants) statements concerning meeting and exceeding regulatory requirements materially misled investors (*Id.* at PageID #1491). Plaintiffs argue that Sotera’s emphasis on its commitment to improving and investing in emissions controls and its purported culture of safety are actionable as securities fraud when those operations are, in reality,

deficient. (*Id.* at PageID #1493–94). Plaintiffs refute Defendants’ arguments that the challenged statements are opinions, inherently aspirational, and/or puffery because these statements were made with the purpose of reassuring investors about matters of importance. (*Id.* at PageID #1496). Nor, according to Plaintiffs, are they protected by the PSLRA Safe Harbor or Bespeaks-Caution Doctrine, because not all of the statements are forward-looking and accompanied by meaningful, cautionary language. Finally, Securities Act Plaintiffs maintain that they have standing to assert their Section 12(a)(2) claim because the Securities Act Selling Shareholders (1) controlled Sotera; (2) caused the issuance of the SPO Prospectus; (3) hired and paid the professionals who conducted the SPO; and (4) received the majority of the SPO proceeds; they assert that these facts support an inference that the Securities Act Selling Shareholders were soliciting the purchase of their own Sotera common stock in the SPO for their own financial gain. (*Id.* at PageID #1507).

Defendants filed a Reply Brief largely restating their Motion arguments (ECF No. 33). This Court held an oral argument on Defendant’s Motion on January 24, 2024, and the matter is now ripe for ruling.

II. LEGAL STANDARD

A. Motion to Dismiss

To survive a motion to dismiss under Fed. R. Civ. P. 12(b)(6), the complaint must “contain sufficient factual matter, accepted as true, to ‘state a claim to relief that is plausible on its face.’” *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007)). The complaint must show more than “labels and conclusions, and a formulaic recitation of the elements of a cause of action.” *Twombly*, 550 U.S. at 555 (citing *Papasan v. Allain*, 478 U.S. 265, 286 (1986)). In determining plausibility, the plaintiff must plead “factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct

alleged.” *Iqbal*, 556 U.S. at 678. The Court “construe[s] the complaint in the light most favorable to the plaintiff, accept[s] its allegations as true, and draw[s] all reasonable inferences in favor of the plaintiff.” *Directv, Inc. v. Treesh*, 487 F.3d 471, 476 (6th Cir. 2007).

When deciding a motion to dismiss under Rule 12(b)(6), the Court may consider “the documents attached to and incorporated by reference into the complaint.” *Katt v. Titan Acquisitions, Ltd.*, 133 F. Supp. 2d 632, 637 (M.D. Tenn. 2000); Fed. R. Civ. P. 10(c). The Court may also examine documents attached to a motion to dismiss “if they are referred to in the plaintiff’s complaint and are central to her claim.” *Schmidt v. PennyMac Loan Servs., LLC*, 106 F. Supp. 3d 859, 865 (E.D. Mich. 2015) (quoting *Weiner v. Klais & Co., Inc.*, 108 F.3d 86, 89 (6th Cir. 1997), *overruled on other grounds*, *Swierkiwicz v. Sorema, N.A.*, 534 U.S. 506 (2002)). In addition, the Court “may consider public records and any other matters of which the court may take judicial notice under Rule 201(b) of the Federal Rules of Evidence.” *Harbison v. Hamilton Cnty., Tenn.*, No. 1:11-cv-178, 2012 WL 1071259, at *3 (E.D. Tenn. Mar. 29, 2012). “[W]ere courts to refrain from considering such documents, complaints that quoted only selected and misleading portions of such documents could not be dismissed under Rule 12(b)(6) even though they would be doomed to failure.” *In re Omnicare, Inc. Sec. Litig.*, 769 F.3d 455, 466 (6th Cir. 2014) (quoting *Kramer v. Time Warner, Inc.*, 937 F.2d 767, 774 (2d Cir. 1991)).

Here, the Court takes judicial notice of the records that follow the internet links cited in the Complaint (ECF No. 24, PageID #573 n.19 & n.20), and the following documents attached to Defendants’ Motion to Dismiss that are referred to in Plaintiffs’ Complaint and/or are central to their claims: the complete IPO Prospectus (ECF No. 31-3, PageID #724–1005); Sotera’s Form 10-K for the fiscal year ending December 31, 2020 (ECF No. 31-4, PageID #1007–161); Sotera’s Form 10-K for the fiscal year ending December 31, 2021 (ECF No. 31-5, PageID #1163–291);

Sotera's public stock price history from November 23, 2020 through January 31, 2023 (ECF No. 31-8, PageID #1332–47); the publicly available judgment and jury verdict in favor of Sotera, Sterigenics, and Griffith Foods in *Fornek* (ECF No. 31-9, PageID #1349–50); and the SPO Prospectus (ECF No. 31-10, PageID #1352–1435).

B. Heightened Pleading Standards Apply to All of Plaintiffs' Claims

1. The Exchange Act Claims

For cases involving fraud, a plaintiff must allege the fraud “with particularity.” Fed. R. Civ. P. 9(b). Specifically, this Rule states that, “[i]n all averments of fraud or mistake, the circumstances constituting fraud or mistake shall be stated with particularity. Malice, intent, knowledge, and other conditions of a person's mind may be alleged generally.” *Id.* To meet the requirements of Rule 9(b), “a plaintiff must at a minimum allege the time, place, and contents of the misrepresentation(s) upon which he relied.” *Bender v. Southland Corp.*, 749 F.2d 1205, 1216 (6th Cir. 1984). “Generalized and conclusory allegations that defendants' conduct was fraudulent do not satisfy Rule 9(b).” *In re FirstEnergy Corp. Sec. Litig.*, 316 F. Supp. 2d 581, 590–91 (N.D. Ohio 2004) (citing *Bovee v. Cooper & Lybrand C.P.A.*, 272 F.3d 356, 361 (6th Cir. 2001)).

Notwithstanding Rule 9(b)'s standard, the Court must also apply the requirements set forth in the Private Securities Litigation Reform Act (“PSLRA”). 15 U.S.C. §78u-4(a)(1). Under the PSLRA, when the plaintiff's claims are based on the defendant's “untrue statement of a material fact” or omission of “a material fact necessary in order to make the statements made, in the light of circumstance in which they were made, not misleading,” the complaint must “specify each statement alleged to have been misleading, the reason or reasons why the statement is misleading, and, if an allegation regarding the statement or omission is made on information and belief, the complaint shall state with particularity all facts on which that belief is formed.” 15 U.S.C. §78u-

4(b)(1). Unlike Rule 9(b), which permits general, less specific pleading of the defendant's knowledge, the PSLRA requires the complaint to "state with particularity facts giving rise to a strong inference that the defendant acted with the required state of mind." 15 U.S.C. §78u-4(b)(2)(A). The Court may dismiss a complaint when a plaintiff does not meet the heightened pleading requirement. 15 U.S.C. §78u-4(b)(3); *Hoffman v. Comshare, Inc. (In re Comshare Inc. Sec. Litig.)*, 183 F.3d 542, 548 (6th Cir. 1999) ("The PSLRA provides that if a plaintiff does not meet this requirement, a court may, on any defendant's motion, dismiss the complaint."). Only those inferences that remain plausible in light of competing inferences are drawn in the plaintiff's favor. *Helwig v. Vencor, Inc.*, 251 F.3d 540, 553 (6th Cir. 2001).

2. *The Securities Act Claims*

The parties disagree on the pleading standard applicable to the Securities Act Plaintiffs' claims. Securities Act Defendants argue that the Securities Act Plaintiffs' claims are all based on the alleged material misrepresentations and concealment of facts known to the Securities Act Officer Defendants, which sound in fraud. (ECF No. 33, Reply Mem. in Support of Mot. to Dismiss, PageID #1522–23). To the extent that Securities Act Plaintiffs claim that Sotera actively sought to suppress regulator and public knowledge of EO's carcinogenic properties, such language is classically associated with fraud, rendering Rule 9(b)'s particularity requirement applicable. (*Id.*).

Securities Act Plaintiffs disagree; they argue that they carefully separated their Securities Act claims from allegations of fraud elsewhere in the Complaint. (ECF No. 32, Mem. in Opp. to Mot. to Dismiss, PageID #1486–87). Securities Act Plaintiffs also repeatedly "disavow any allegations or averments of fraud in connection with the claims pleaded" under the Securities Act. (ECF No. 24, PageID #595; *see id.* at PageID #617, 620, 623, 624 ("This Count expressly excludes

and disclaims any allegation that could be construed as alleging fraud or intentional or reckless conduct, as this Count is solely based on claims of strict liability and/or negligence under the Securities Act”)).

Generally, “fraud is not an element or requisite to a claim under § 11,” and so these claims are not always subject to Rule 9(b). *In re FirstEnergy Corp. Sec. Litig.*, 316 F. Supp. 2d 581, 602 (N.D. Ohio 2004). But when such claims sound in fraud, “[p]laintiffs must also satisfy the particularity requirement in Rule 9(b).” *In re FirstEnergy Corp.*, Nos. 2:20-cv-3785 & 2:20-cv-4287, 2022 WL 681320, at *33 (S.D. Ohio Mar. 17, 2022) (citing *In re EveryWare, Inc. Sec. Litig.*, 175 F. Supp. 3d 837, 869 (S.D. 2006), *aff’d*, 849 F.3d 325, 328 (6th Cir. 2017); *Ind. State Dis. Council of Laborers & Hod Carriers Pension & Welfare Fund v. Omnicare, Inc.*, 583 F.3d 935, 948 (6th Cir. 2009)).

Claims that sound in fraud are premised on a unified course of fraudulent conduct and rely entirely on that course of conduct as the basis of such claim. *Rubke v. Capitol Bancorp Ltd.*, 551 F.3d 1156, 1161 (9th Cir. 2009). In other words, “when fraud pleadings under Section 10(b) of the [Exchange Act] employ the same facts as a [Securities Act] Section 11 claim or a 12(a)(2) claim, we can assume that the complaint sounds in fraud.” *Kolominsky v. Root, Inc.*, 100 F.4th 675, 683 (6th Cir. 2024) (citing *Rubke*, 51 F.3d at 1161; *Frank v. Dana Corp.*, 547 F.3d 564, 569–70 (6th Cir. 2008)). Only when a plaintiff “carefully distinguishes the fraud claims from other claims” does Fed. R. Civ. P. 8(a) govern the pleading standard. *Id.* (citing *In re EveryWare Glob., Inc. Sec. Litig.*, 175 F. Supp. 3d at 869–70). In *Kolominsky*, the plaintiffs presented Exchange Act and Securities Act claims separately, disclaiming allegations of fraud in the latter, but relied on a single set of facts that alleged the defendant made materially false and misleading statements and omissions. 100 F.4th at 684. The Court found that, despite the separation of the claims and

disclaimer language, reliance on a single set of facts that sound in fraud bind the whole of the complaint to the particularity requirement of Rule 9(b). *Id.*

The Court agrees with the Securities Act Defendants. While Plaintiffs' Securities Act claims are asserted in a separate section of the Complaint, delineating different parties and different claims under a different securities statute, the claims are all based on Sotera's alleged fraud and material misrepresentations. For example, under the section of the Securities Act Complaint titled, "Actionable Statements and Omissions in the IPO Offering Materials and SPO Offering Materials," Plaintiffs quote the following:

We are investing in additional voluntary controls on EO emissions at our facilities to outperform current and expected future regulatory requirements and further reduce facility emissions. . . . We consistently meet and outperform regulatory emissions control requirements, although we have experienced instances of emissions exceeding applicable standards, none of which we believe were material. We expect to be able to satisfy any changes to applicable regulatory requirements as they evolve.

(ECF No. 24, PageID #609). This same statement in Sotera's IPO Offering Materials is used to support Exchange Act Plaintiffs' Section 10(b) and Rule 10b-5(a-c) claims. (*Id.* at PageID #505-06). Securities Act Plaintiffs allege this is an "untrue statement of material fact when made or omitted to state material facts required to be stated therein or necessary to make the statements therein not misleading" because

[i]n truth, Sotera and its predecessors were aware of the carcinogenic risk that EtO posed to the surrounding communities since at least the early 1980s, yet chose not to employ adequate and effective EtO emissions controls systems at its sterilization facilities and often subverted whatever control systems the Company did have, allowing dangerous amounts of toxic EtO fumes to pollute the air surrounding those facilities and exposing people living in the adjacent communities to significantly increased cancer risk and the Company to an increased headline risk, risk of regulatory scrutiny, and liability from hundreds of EtO related lawsuits. Sotera also failed to comply with the terms of several of the permits it received from state and federal regulators designed to monitor and decrease emissions, and instead of being "proactive" regarding environmental safety actively sought

to suppress regulator and public knowledge of EtO's carcinogenic properties. Finally, rather than focusing on compliance, health, or safety, for years prior to and throughout the Class Period, Defendants actively engaged in efforts to minimize, reduce and evade the regulation and regulatory impact of EtO.

(*Id.* at PageID #610 (the "Securities Act Explanation")). Moreover, Exchange Act Plaintiffs recite very similar (at times, word-for-word) reasons for their belief that such statement was "materially false and misleading":

These statements were materially false and misleading because Sotera's executives and controlling shareholders knew of the significant health risks associated with exposure to elevated levels of EtO. Despite that knowledge, Sotera chose not to employ adequate and effective emissions control systems at its sterilization facilities, and often subverted whatever control systems the Company did have, allowing dangerous amounts of toxic EtO fumes to pollute the air surrounding those facilities and exposing people living in the adjacent communities to significantly increased cancer risk. Over the life of the Willowbrook facility, Sotera also failed to comply with requirements in multiple permits designed to limit and monitor EtO emissions. Even after Sotera's closure of its Illinois EtO processing plant, the Company failed to adequately enhance emissions controls and continued to operate multiple sterilization facilities that emitted dangerous levels of EtO during the Class Period and beyond. Far from a "proactive" culture of safety, Sotera actively sought to prevent regulators and the public from learning about the carcinogenic properties of EtO.

(*Id.* at PageID #507 (the "Exchange Act Explanation")). The changed words between these two sections of the Complaint do little to meaningfully differentiate them from one another. The gist of both sections is that (1) Officer Defendants had known that EO was a toxic carcinogen for a long time; (2) even with that knowledge, Sotera did not use an emission control system designed to protect its employees or the public, often subverting those controls and allowing EO gas to escape the facilities; (3) Sotera did not consistently comply with its permits meant to limit and track its EO emissions; (4) Sotera did not enhance emissions controls; and (5) Sotera's claims that it was "proactive" about health and safety are contradicted by its efforts to hide the ultimate harmfulness of EO sterilization to the public. There is no difference in meaning between these

two paragraphs, and they appear in support of both the Exchange Act claims and the Securities Act claims.

The Complaint is rife with additional examples. (*Compare, e.g., id.* at PageID #499 [Exchange Act] *with id.* at PageID #611 [Securities Act], using same Explanations described above to assign liability; *id.* at PageID #500 [Exchange Act] *with id.* at PageID #612 [Securities Act], using similar explanations described above to assign liability; *id.* at PageID #511 [Exchange Act] *with id.* at PageID #613 [Securities Act], where the Exchange Act Explanation is identical to the above-quoted Securities Act Explanation, and the Securities Act Explanation is very similar thereto).

Like *Kolominsky*, Securities Act Plaintiffs attempted to segregate the Securities Act claims from the Exchange Act Plaintiffs' claims by quartering them in individual sections of the Complaint and disclaiming any allegations of fraud; but also like *Kolominsky*, Securities Act Plaintiffs relied on the same facts presented by the Exchange Act Plaintiffs in support of their Section 10(b) and Rule 10b-5 claims. These claims sound in fraud, and therefore, they must meet the particularity requirement of Rule 9(b).

III. LAW & ANALYSIS

A. Exchange Act Plaintiffs Failed to Allege Actionable Misstatements or Omissions with Particularity

1. Applicable Legal Standard to "False and Misleading" Statements

a. Section 10(b) and Rule 10b-5(a)-(c)

The Exchange Act Plaintiffs failed to state a claim for which relief can be granted because they failed to plead an actionable material misrepresentation or omission with particularity as required by Fed. R. Civ. P. 9(b). They also failed to meet the PSLRA's heightened pleading standard.

Count One brings claims against Sotera, Petras, Leffler, and the Exchange Act Director Defendants under Section 10(b) and Rule 10b-5(b). Section 10(b) states that it is “unlawful for any person . . . [t]o use or employ, in the connection with the purchase or sale of any security . . . , any manipulative or deceptive device” 15 U.S.C. § 78j(b). The SEC created Rule 10b-5(b) under Section 10(b) of the Exchange Act, establishing that it is “unlawful for any person, directly or indirectly, by use of any means or instrumentality of interstate commerce, or the mails or any facility of any national securities exchange, . . . (b) [t]o make any untrue statement of material fact or to omit a material fact necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading.” 17 C.F.R. §240.10b-5(b).

Count Two brings a “scheme liability” claim against Sotera and Officer Defendants under Section 10(b) and Rule 10b-5(a) and (c). Rule 10b-5(a) provides that it is “unlawful for any person, directly or indirectly, by use of any means or instrumentality of interstate commerce, or of the mails or of any facility of any national securities exchange, (a) [t]o employ any device, scheme, or artifice to defraud.” 17 C.F.R. § 240.10b-5(a). Subsection (c) makes it unlawful for any person by those same means “[t]o engage in any practice or course of business which operates or would operate as a fraud or deceit upon any person.” 17 C.F.R. § 240.10b-5(c).

For a party to prevail on a claim under Section 10(b) and Rule 10b-5, the party must demonstrate:

- (1) a material misrepresentation or omission by the defendant; (2) scienter;
- (3) a connection between the misrepresentation or omission and the purchase or sale of a security; (4) reliance upon the misrepresentation or omission; (5) economic loss; and (6) loss causation.

Matrixx Initiatives, Inc. v. Siracusano, 563 U.S. 27, 37–38 (2011) (citing *Stoneridge Inv. Partners, LLC v. Sci.-Atlanta, Inc.*, 552 U.S. 148, 157 (2008)). When a plaintiff “fails to plausibly allege even one of these elements, a securities-fraud claim cannot proceed.” *Pittman v. Unum Grp.*, 861

F. App'x. 51, 53 (6th Cir. 2021). This analysis will address only the first element of this test as it applies to both Counts One and Two.

b. Materiality

A misrepresentation is material and a factual omission occurs when “there is a substantial likelihood that a reasonable shareholder would consider it important” or “the disclosure of the omitted fact would have been viewed by the reasonable investor as having significantly altered the ‘total mix’ of information made available.” *Basic Inc. v. Levinson*, 485 U.S. 224, 231–32 (1988) (quoting *TSC Indus. v. Northway*, 426 U.S. 438, 449 (1976)). For statements or omissions to be actionable, they must be “false or misleading at the time that they were made.” *In re Omnicare, Inc. Sec. Litig.*, 769 F.3d 455, 471 (6th Cir. 2014); *Hall v. Johnson & Johnson*, No. 18-1833, 2019 WL 7207491, at *12 (D.N.J. Dec. 27, 2019) (citing *In re NAHC, Inc. Sec. Litig.*, 306 F.3d 1314, 1330 (3d Cir. 2002)).

Since materiality is a mixed question of law and fact, statements will only be considered nonactionable when “they are so obviously unimportant to a reasonable investor that reasonable minds could not differ on the question of their unimportance.” *In re Ford Motor Co. Sec. Litig.*, 381 F.3d 563, 570 (6th Cir. 2004) (quoting *Helwig v. Vencor, Inc.*, 251 F.3d 540, 563 (6th Cir. 2001) (en banc)). Determining materiality can be difficult when the statements contain “soft” information, i.e., “statements of subjective analysis or extrapolation, such as opinions, motives, and intentions, or forward looking statements, such as projections, estimates, and forecasts.” *Johnson & Johnson*, 2019 WL 7207491, at *12 (citing *Craftmatic Sec. Litig. v. Kraftsow*, 890 F.2d 628, 642 (3d Cir. 1989)).

Section 10(b) and Rule 10b-5 “do not create an affirmative duty to disclose any and all material information.” *Matrixx Initiatives, Inc. v. Siracusano*, 563 U.S. 27, 44 (2011). “Silence,

absent a duty to disclose, is not misleading under Rule 10b-5.” *Basic*, 485 U.S. at 239 n.17. An omitted statement may become actionable where there is a duty to disclose information. Such duty exists when the disclosure is required by statute or “when an ‘inaccurate, incomplete or misleading prior’ statement exists.” *Lim v. Hightower*, Case No. 4:23CV1454, 2024 WL 4349409, at *9 (N.D. Ohio Sept. 30, 2024) (quoting *City of Monroe Emps. Ret. Sys. v. Bridgestone Corp.*, 399 F.3d 651, 669 (6th Cir. 2005)). The prior statement also “must have been **materially** misleading at the time it was made.” *Johnson & Johnson*, 2019 WL 7207491, at *12 (emphasis added) (citing *In re NAHC, Inc. Sec. Litig.*, 306 F.3d at 1330); *Basic*, 485 U.S. at 238 (“It is not enough that a statement is false or incomplete, if the misrepresented fact is otherwise insignificant.”); *Dailey v. Medlock*, 551 F. App’x 841, 845 (6th Cir. 2014) (explaining that disclosure is only required under § 10(b) and Rule 10b-5 when necessary to make a company’s statements, in the context in which they were made, not misleading).

The duty to disclose material information is further limited in the Sixth Circuit to that which constitutes “hard” information, which “is typically historical information or other factual information that is objectively verifiable. Such information is to be contrasted with ‘soft’ information, which includes predictions and matters of opinion.” *Zaluski v. United Am. Healthcare Corp.*, 527 F.3d 564, 572 (6th Cir. 2008) (quoting *In re Sofamor Danek*, 123 F.3d 394, 401 (6th Cir. 1997)). Soft information requires disclosure only when it is “virtually as certain as hard facts.” *Id.* (citing *City of Monroe Emps. Ret. Sys. v. Bridgestone Corp.*, 399 F.3d 651, 669 (6th Cir. 2005)). Moreover, actionable soft information requires the plaintiff to “allege particular facts demonstrating that defendants had actual knowledge that their statements concerning soft information were false or misleading at the time that they were made.” *In re Omnicare, Inc. Sec. Litig.*, 769 F.3d 455, 470 (6th Cir. 2014).

The reason for the delineation between “hard” and “soft” information is practical; absent further limitations, “corporations might otherwise ‘face potential second-guessing in a subsequent disclosure suit,’ a regime that would threaten to ‘deluge investors with marginally useful information and would damage corporations’ legitimate needs to keep some information non-public.” *Zaluski*, 527 F.3d at 572 (citing *Bridgestone*, 399 F.3d at 669). Thus, “soft” information, like opinions, puffery, and corporate optimism tend to be immaterial. *In re Ford Motor Co. Sec. Litig.*, 381 F.3d 563, 570 (6th Cir. 2004) (explaining that a reasonable investor would not view corporate puffery or hyperbole “as significantly changing the general gist of available information,” rendering the information immaterial); *Omnicare, Inc. v. Laborers Dist. Council Constr. Indust. Pension Fund*, 575 U.S. 175, 184 (2015) (“[A]lthough a plaintiff could later prove that opinion erroneous, the words ‘I believe’ themselves admitted that possibility, thus precluding liability for an untrue statement of fact.”). Materiality of soft information is judged from the perspective of a reasonable investor. *Omnicare, Inc.*, 575 U.S. at 186.

c. The PSLRA Safe Harbor

In addition to the limitation on liability where information is deemed to be “soft,” the PSLRA has a “safe-harbor” provision that protects forward-looking statements from liability:

[The safe harbor] provision excuses liability for defendants’ projections, statements of plans and objectives, and estimates of future economic performance. A plaintiff may overcome this protection only if the statement was material; if defendants had actual knowledge that it was false or misleading; and if the statement was not identified as “forward-looking” or lacked meaningful cautionary statements.

Zaluski, 527 F.3d at 572 (quoting *Helwig v. Vencor, Inc.*, 251 F.3d 540, 547–48; 15 U.S.C. § 78u-5(c)(1)). Statements are forward looking when, at the time they were made, the accuracy of the statement could not be determined. *Lim v. Hightower*, No. 4:23CV1454, 2024 WL 4349409, at *9 (N.D. Ohio Sept. 30, 2024) (citing *La. Sheriffs’ Pension & Relief Fund v. Cardinal Health, Inc.*,

No. 2:19-cv-3347, 2021 WL 4397946, at *12 (S.D. Ohio Sept. 27, 2021)). Forward-looking statements include statements related to future planning, objectives, economic performance and earnings, and financial conditions. 15 U.S.C. §78u-5(i).

But a forward-looking statement can nevertheless fall outside the PSLRA safe harbor; the disclosure of forward-looking statements “must be full and fair, and courts may conclude that the company was obliged to disclose additional material facts to the extent that the volunteered disclosure was misleading.” *Zaluski*, 527 F.3d at 572 (quoting *Helwig*, 251 F.3d at 564). Thus, when it comes to forward-looking statements, the court must ask whether liability may flow from the company’s decision to speak about material details “without revealing certain additional known facts necessary to make [its] statements not misleading.” *Id.* (quoting *Rubin v. Schottenstein, Zox & Dunn*, 143 F.3d 263, 267 (6th Cir. 1998)). This makes sense; this exception to the PSLRA safe harbor merely echoes Rule 10b-5 itself by requiring a company’s factual statements to include all material information known to the company at the time the statement is made to ensure that the statement is not misleading. *Id.* (quoting *Rubin*, 143 F.3d at 267; 17 C.F.R. § 240.10b-5(b)).

The PSLRA safe harbor is cumulative; materiality, actual knowledge of falsity, and failure to identify the statement as “forward looking” alongside cautionary language must all be shown to avoid its protection of the statement at issue. *Miller v. Champion Enters., Inc.*, 346 F.3d 660, 672 (6th Cir. 2003) (noting that regardless of scienter, forward-looking statements made with cautionary language are protected by PSLRA); *Helwig*, 251 F.3d at 548. Furthermore, Congress “intended the applicability of the safe harbor to be addressed even on a motion to dismiss.” *Helwig*, 251 F.3d at 554 (citing 15 U.S.C. § 78u-5(e) (instructing courts to consider “any cautionary statement accompanying the forward-looking statement” upon a motion to dismiss based on the safe harbor provisions)).

2. *Exchange Act Plaintiffs Fail to Allege an Actionable Materially False or Misleading Misstatement or Omission with Particularity*

As an initial matter, Exchange Act Plaintiffs satisfy the first prong of the PSLRA in that they have specified each allegedly misleading statement; the Complaint contains more than 50 pages of allegedly false and misleading statements, the dates upon which those statements were made, and the location of each statement. (ECF No. 24, PageID #498–552). Exchange Act Plaintiffs failed, however, to plead with particularity that these statements are actionable under the Exchange Act, or that they were false or misleading when made.

a. Permit/Regulatory Statements

The Court first addresses the statements that Exchange Act Plaintiffs claim to be false and misleading that concern Sotera’s permit and regulatory compliance. Exchange Act Plaintiffs allege that it was false and misleading to claim that the company would “continue to comply with all permits” and had “many decades” of regulatory compliance when, over the life of the Willowbrook facility, Sotera failed to comply with permits designed to limit and monitor EO emissions. (*Id.* at PageID #503–04; 513; 542).

“[A] generic claim of legal compliance, absent any specifics, does not form the basis for a misrepresentation actionable under Rule 10b-5.” *Dailey v. Medlock*, 551 F. App’x 841, 849 (6th Cir. 2014) (citing *Ind. State Dist. Council of Laborers & Hod Carriers Pension & Welfare Fund v. Omnicare, Inc.*, 583 F.3d 935, 945–47 (6th Cir. 2009) (rejecting 10b-5 claim relating to “legal compliance” when claim lacked significant factual support)). That is because “legal compliance” statements are usually considered “soft,” making them inactionable under the Exchange Act. *Omnicare, Inc.*, 583 F.3d at 945. In *Omnicare*, the Sixth Circuit affirmed a district court’s ruling that the company’s general assertions of legal compliance—that it “complied with state law and

regulations and had a policy of complying with the law”—were not actionable because the plaintiffs failed to show the defendants knew the statements were untruthful. *Id.* at 945–47.

Omnicare cited to *Kushner v. Beverly Enters., Inc.*, 317 F.3d 820 (8th Cir. 2003) for guidance. *Id.* at 945–46. In *Kushner*, a company generally asserted that it complied with Medicare regulations but was later involved in a significant Medicare fraud investigation. 317 F.3d at 824–25, 830–31. The Eighth Circuit did not reject the notion that liability could attach to a company’s general assertion of legal compliance, but insisted that a successful complaint must “adequately plead[] that the defendants knew the statements were untruthful.” *Id.* at 831. Absent such allegations, the pleading was deemed inadequate. *Id.*

Plaintiffs complain that Sotera failed to control emissions pursuant to a permit it submitted 41 years ago by Sotera’s predecessor, Griffith⁶, but the Complaint does not allege violations of that permit; rather, the Complaint alleges that the Willowbrook emissions “led to and directly created risk of adverse liability rulings, regulatory action, reputation harm and business interruptions.” (*Id.* at PageID #470–71). Plaintiffs also cite to testimony from the *Kamuda* trial identifying certain testing requirements that were made part of a permit, with which Griffith’s corporate representative could not locate evidence of compliance (or noncompliance). (*Id.* at PageID #473). Plaintiffs do not allege any regulatory actions or sanctions relating to the 1984 Willowbrook permit. (*Id.* at PageID #474). The other permit that Plaintiffs claim Sotera did not comply with is a permit first

⁶ Griffith Laboratories opened a commercial sterilization facility in Willowbrook in April 1984 pursuant to a permit obtained from the IEPA. (ECF No. 24, PageID #453). In 1999, the division of Griffith that conducted EO sterilization at Willowbrook, Griffith Micro Science, was acquired by Ion Beam Applications (“IBA”). IBA also acquired Sterigenics International, a Griffith competitor. (*Id.*). IBA likewise owned the Netherlands facility, which began conducting EO sterilization no later than 2002. (*Id.*). In 2004, Silverfleet Capital acquired the plants formerly owned by Griffith and Sterigenics from IBA, as well as the Netherlands facility. (*Id.*). In March 2011, Defendant GTCR caused the funds it managed to acquire Sterigenics, and installed Michael Mulhern as the CEO. (*Id.* at PageID #453–54). In 2015, Sterigenics acquired Nordion, a supplier of Cobalt 60 (Co-60). (*Id.* at PageID #455). In May 2015, GTCR sold a majority stake in Sterigenics to Defendant Warburg. (*Id.* at PageID #456). Finally, in 2017, Sterigenics International rebranded as Sotera, though its EO sterilization company remained “Sterigenics.” (*Id.*).

obtained in 2000, also relating to Willowbrook. (*Id.* at PageID #475). The Complaint alleges that Sotera's predecessor was out of compliance with this permit for four years before the company obtained approval from regulators to disconnect back vents, mitigating its prior non-compliance. (*Id.* at PageID #477). No specific regulatory violations are alleged in the Complaint beyond these permits.

The Complaint fails to allege that the permit and regulatory statements are false and misleading with particularity, violating both Rule 9(b) and the PSLRA. Plaintiffs identify only two permits over more than 40 years with which Sotera allegedly maintained questionable compliance; Exchange Act Plaintiffs do not allege *any* violation of the first permit, and they admit that the second permit was ultimately complied with via a change made by regulators, not Sotera.

Furthermore, Sotera's affirmative statements to investors and the public do not imply a lack of compliance. For example, when Sotera told investors it was pursuing enhancements (ECF No. 24, PageID #502), continuous improvements (*id.* at PageID #541), and significant investments (*id.* at PageID #535) in EO emissions controls, it did not imply that Sotera had always controlled EO emissions perfectly; indeed, all three of those efforts imply a desire to increase emissions controls beyond a prior, lesser control standard. Petras told attendees of the JP Morgan 39th Annual Healthcare Virtual Conference that the New Mexico Attorney General "asked for improvements" in its Santa Teresa sterilization facility, and that Sotera was "aggressively pursuing facility enhancements across all of our EO facilities in the United States." (*Id.* at PageID #502).

The IPO and SPO Registration Materials provided investors during the Class Period with information about Sotera's history of regulatory and permit compliance, or lack thereof. For example, the IPO Prospectus (and thus, the SPO Prospectus) provided investors with information about the IEPA's shutdown of the Willowbrook facility and the temporary shutdown of the Atlanta

facility, both based on negative regulatory findings. (ECF No. 31-3, PageID #752–53). Sotera informed investors that changes in environmental health and safety regulation have the potential to negatively impact its business, and that compliance is expensive. (*Id.* at PageID #749; 755). The IPO Prospectus went on to state that, despite Sotera’s efforts to comply, “we have not always been and may not always be in compliance and, as a result, can be subject to significant civil and criminal fines and penalties, including the shutdown of our operations or the suspension of licenses, permits or registrations.” (*Id.* at PageID #756). The 2020 Form 10-K similarly stated, “We consistently meet and outperform regulatory emissions control requirements, *although we have experienced instances of emissions exceeding applicable standards, none of which we believe were material.*” (ECF No. 24, PageID #505).

Even after the IPO and SPO, Petras acknowledged that some past regulations were unpredictable by Sotera, and that future, yet-to-be-imposed regulations remain unknown. (*Id.* at PageID #509; 521). In light of these acknowledgments, Petras went on to tell investors that Sotera was nonetheless well-positioned to comply with future regulations based on the enhancements and investments Sotera was making. (*Id.*). Later, in Sotera’s Q2 2021 Form 10-Q, Sotera provided investors with details about the preliminary injunction to which it was subject in the regulatory action filed by the New Mexico Attorney General, and that Sotera had taken steps to monitor its compliance with that order. (*Id.* at PageID #519). Sotera disclosed that it had been working on implementing enhancements to its EO emissions controls in New Mexico, and that it recently received a permit allowing Sotera to implement those controls. (*Id.* at PageID #520).

The Complaint does not allege any basis for the belief that these statements are materially false or misleading, nor could it; Petras could not, at any time alleged in the Complaint, predict the particulars of regulations that had not yet been promulgated. Exchange Act Plaintiffs have not

alleged that Sotera *had not* been significantly investing in enhancements and improvements to its EO emissions controls. The claims relating to permit and regulatory compliance are not challenged with specific facts showing that Sotera or Officer Defendants knew it was *not* complying with regulations when those statements were made; thus these statements, like those in *Omnicare* and *Kushner*, do not meet the particularity requirements of either Rule 9(b) or the PSLRA, and cannot support Exchange Act Plaintiffs' Rule 10b-5 claims.

To the extent that Plaintiffs claim Sotera's former employees put Sotera and its executives on notice of severe regulatory and permit noncompliance, it is not alleged in the Complaint. (*See id.* at PageID #480–88, detailing accounts of former employees). In *Omnicare*, the Sixth Circuit considered statements made by confidential witnesses showing that the company had engaged in illegal drug-handling practices, but discounted them because none of those confidential witnesses communicated any of their concerns to the named defendants. *Ind. State Dist. Council of Laborers & Hod Carriers Pension & Welfare Fund v. Omnicare, Inc.*, 583 F.3d 935, 946 (6th Cir. 2009). In another matter, *In re Huntington Bancshares Inc. Sec. Litig.*, 674 F. Supp. 2d 951, 963–64 (N.D. Ohio 2009), this Court reviewed the statements of numerous confidential witnesses/former employees and found that they were insufficient to demonstrate that the company knew the statements at issue were false when made; none of the former employees were alleged to have firsthand knowledge about claims in the complaint; none alleged that the named defendants in that case had firsthand knowledge of the same claims; none alleged that they communicated their concerns to any of the named defendants; none alleged that the named defendants committed fraud or disseminated false information; and none alleged that the named defendants had information that was not reflected in the applicable disclosures and SEC filings. *Id.*

Exchange Act Plaintiffs make the same logical error that the plaintiffs in both *Omnicare* and *Huntington Bancshares* made; they claim that statements by Sotera's former employees about the conditions in Sotera's facilities should have put Exchange Act Defendants on notice that their statements about regulatory and permit compliance were false. (ECF No. 32, PageID #1491–92). Former Employees 2–6 all worked for Sotera before the Class Period began. None were tasked with (or claim particularized knowledge regarding) regulatory compliance efforts or monitoring, and none claim to have notified any of the Exchange Act Defendants of what they saw as dangerous practices relating to EO. (ECF No. 24, PageID #481-86). The most damning statement contained in this section of the Complaint comes from David Marsh, a former Sotera employee, who was tasked with investigating possible EO leaks throughout Sotera's facilities in 2012. (*Id.* at PageID #486–87). Mr. Marsh contracted leukemia, allegedly as the result of this task; but his public statements about that investigation were not made until May 2, 2023—long after all the alleged misleading statements described in the Complaint were made. (*Id.*).

Like the employees discussed in *Huntington Bancshares*, the former employees do not explain why Exchange Act Defendants' statements were misleading or fraudulent. *Huntington Bancshares*, 674 F. Supp. 2d at 963. Moreover, Sotera had no duty to affirmatively tell its investors of its legal compliance failures. *Omnicare*, 583 F.3d at 946. Exchange Act Plaintiffs present nothing to the Court that suggests Sotera was *not* engaging in the compliance efforts that it told investors it was making, and Sotera did not deliver to investors an unequivocal message of universal compliance. Instead, Sotera told investors that it was making particularized efforts to improve beyond a prior, lesser emissions control standard, which is, at minimum, consistent with what the former employees describe.

Finally, the Court finds that Sotera’s generalized statements about its position in a highly regulated market are “soft” information, amounting to matters of opinion and corporate optimism, none of which would be relied upon by a reasonable investor. For example, Sotera claimed it had “a high degree of confidence” in its ability to comply with any regulatory requirement”; that Sotera has “proven over the years our ability to comply with any new regulatory requirements”; that it “believe[s] that [it’s] an industry leader and ha[s] a competitive advantage” in regulatory compliance efforts; and that it has a “track record of compliance.” (ECF No. 24, PageID #502–04; 513; 524; 531; 535; 541–42). No reasonable investor would consider these statements “virtually as certain as hard facts,” and thus, Sotera was under no obligation to correct them with admissions of regulatory non-compliance, such as the South Coast AQMD’s 2022 Notices of Violation—the only Class-Period regulatory violations alleged in the Complaint. *See Ind. State Dist. Council of Laborers & Hod Carriers Pension & Welfare Fund v. Omnicare, Inc.*, 583 F.3d 935, 947 (6th Cir. 2009) (explaining that a company’s “generic claim of lawfulness, in the absence of any specifics, [does not] require the disclosure of the allegedly ‘illegal’ activities”); *In re Gentiva Sec. Litig.*, 932 F. Supp. 2d 352, 370 (E.D.N.Y. 2013) (“[Statements] that the compliance program was ‘robust’ or ‘best-of-class’ . . . were too general to cause reliance by a reasonable investor.”).

As such, Exchange Act Plaintiffs fail to state actionable misstatements or omissions regarding Sotera’s regulatory and permit compliance with particularity. These statements cannot support Exchange Act Plaintiffs’ Section 10(b) and Rule 10b-5 claims.

d. Litigation-Based Statements

Turning to Sotera’s litigation-based statements, Exchange Act Plaintiffs aver that it was materially false and misleading for Exchange Act Defendants to deny the allegations asserted against them in the Willowbrook EO litigation and tell investors that Sotera planned to “vigorously

defend against” those claims. (ECF No. 24, PageID #510; 516; 539). Exchange Act Plaintiffs likewise argue that it was false and misleading for Sotera not to take a contingency reserve related to the litigation when Sotera’s loss in that litigation was likely based on its knowledge of its failures to adequately control EO emissions. (*Id.* at PageID #516). Exchange Act Plaintiffs claim that Sotera’s denial that it caused the cancer alleged in the Willowbrook EO litigation was false and misleading for the same reason; it knew it was not doing enough to control EO emissions from its facilities. (*Id.* at PageID #524).

The Court first notes that investors were on notice of the state of Sotera’s EO litigation from the beginning of the Class Period. The IPO Prospectus provided investors with an abundance of information about the pending litigation against Sotera: Sotera provided detailed descriptions of the Willowbrook EO tort and government litigation; multiple proceedings in Georgia concerning (1) community and employee EO exposure in and around Sotera’s facilities, (2) claims that Sotera’s facilities reduced property values, and (3) regulatory litigation that temporarily closed Sotera’s Atlanta facility; and the Zoetermeer, Holland criminal case relating to EO emissions. (ECF No. 31-3, PageID #845–49). Potential investors were on notice from the beginning of the Class Period that these suits were ongoing, and they knew the details. Exchange Act Plaintiffs have not alleged that any of these statements of fact were false or misleading.

Regarding the ongoing litigation described in the IPO Prospectus and discussed by Exchange Act Officer Defendants thereafter, a company does not have a duty to “disclose uncharged, unadjudicated wrongdoing.” *Lubbers v. Flagstar Bancorp. Inc.*, 162 F. Supp. 3d 571, 582 (E.D. Mich. 2016) (quoting *City of Pontiac Policemen’s & Firemen’s Ret. Sys. v. UBS AG*, 752 F.3d 173, 184 (2d Cir. 2014)); *In re Facebook, Inc. Sec. Litig.*, 405 F. Supp. 3d 809, 836 (N.D. Cal. 2019) (“companies are not required to engage in ‘self-flagellation’ by disclosing unproven

allegations”). *Hall v. Johnson & Johnson*, No. 18-1833, 2019 WL 7207491, (D.N.J. Dec. 27, 2019), to which both parties cite, has notable similarities and differences to the case presented here. (See ECF No. 32, PageID #1493; ECF No. 33, PageID #1526). The Court finds this case to be a helpful tool for comparison to the allegedly misleading litigation statements recited in the Complaint.

Johnson & Johnson concerned the company’s now well-known cosmetic talc litigation. Prior to that litigation, in which the company’s cosmetic talc was found to contain asbestos and cause various types of cancer, the *Johnson & Johnson* plaintiffs alleged that the company “concealed the truth about the asbestos in its Talc Products through a highly organized campaign of deceit and regulatory manipulation.” *Id.* at *3. Like EO, cosmetic talc is a naturally occurring substance with carcinogenic properties, and concerns about its safe usage emerged around 50 years ago. *Id.*

The *Johnson & Johnson* plaintiffs presented the court with a host of evidence demonstrating the company’s knowledge of cosmetic talc’s dangers: internal company documents showed that the company’s doctors and employees knew in 1969 that cosmetic talc may be damaging babies’ and mothers’ lungs; the company acknowledged testing from outside laboratories throughout the 1970’s demonstrating the presence of asbestos in its cosmetic talc, but did its best to hide that information from regulators and the public; the company actively avoided testing methods that would affirmatively show asbestos in its cosmetic talc; because there was nothing the company could do about the asbestos in cosmetic talc, the company tried to control the independent scientific community’s research by sponsoring its own studies and taking steps to preclude the National Toxicology Program (“NTP”) from even considering whether cosmetic talc was a potential carcinogen; and when the NTP did engage in testing, the company assigned

executives to “defend talc” by hiring an outside law firm, which in turn hired experts, “to develop documents” that undermined the link between talc and cancer. *Id.* at *3–4. The company celebrated when the NTP withdrew cosmetic talc as a listed carcinogen in 2005. *Id.*

Even after the talc lawsuits began, and even after verdicts against the company were rendered in 2013, the company’s website was updated to state, “[f]ew ingredients have demonstrated the same performance, mildness and safety profile as cosmetic talc, which has been used for over 100 years” and has “a long history of safe use.” *Id.* at *5. The website maintained that the company’s cosmetic talc was “carefully selected, processed and tested to ensure that [it was] asbestos free.” *Id.* Such testing, the company claimed, had been “confirmed by regular testing conducted since the 1970s.” *Id.* Another verdict was entered against the company in 2016 for personal injuries due to the company’s failure to warn, negligence, and conspiracy related to its cosmetic talc (but not, specifically, the asbestos within the talc). *Id.*

After the 2016 verdict, the company presented false information to the FDA disclaiming the presence of asbestos in its cosmetic talc; the company continued to suppress its decades of affirmative asbestos testing, telling the investing public that its product did not contain asbestos, that it was routinely tested for the presence of asbestos “to ensure quality, safety, and compliance with all global standards”; and claimed, “[t]he safety of talc is based on a long history of safe use and decades of research by independent researchers and scientific review boards.” *Id.* The company’s bubble burst between 2017 to 2018, when—as the Exchange Act and Securities Act Plaintiffs allege here—the “truth emerged,” and the company’s stock declined. *Id.*; (ECF No. 24, PageID #558). When a new type of lawsuit was brought against the company, this time, a plaintiff specifically alleging that the asbestos in the company’s talc caused his mesothelioma, news outlets began publishing the company’s internal documents showing that the company knew as early as

the 1970s that its product contained asbestos. *Johnson & Johnson*, 2019 WL 7207491, at *6. The company's stock further declined. *Id.* The verdict in that lawsuit again went against the company; nonetheless, a company executive told *New York Daily News* that "Johnson's Baby Powder has been used for more than 120 years and it does not contain asbestos or cause mesothelioma," and "[w]e believe that once the full evidence is reviewed, this decision will be reversed." *Id.* Other company executives went to other outlets and conferences and made similar statements. *Id.*

A few months later, the company lost a \$4.69 *billion* verdict in a case where the plaintiffs alleged their ovarian cancer was caused by asbestos in the company's cosmetic talc, and the company's stock continued its decline. *Id.* at *7. The company's public messaging remained unchanged; in a July 2018 corporate statement, and again during an earnings call the same month, the company claimed that the evidence in this case "was simply overwhelmed by the prejudice" the company suffered in the press, and that it "remains confident that its products do not contain asbestos and do not cause ovarian cancer." *Id.* In December 2018, after *Reuters* published a detailed investigative report called, "Powder Keg: Johnson & Johnson knew for decades that asbestos lurked in its Baby Powder," the company's stock fell another 10%. *Id.* The securities class action lawsuit cited here followed; plaintiffs sued the company for violations of Section 10(b) and Rule 10b-5, and Rule 20(a) of the Exchange Act. *Id.* at *8.

The *Johnson & Johnson* court found that the company's statements about the litigation—even those statements that followed negative verdicts—amounted to "opinions regarding the success of the litigation, rather than statements of fact." The Court went on to state:

Plaintiff's argument on this point is, essentially, that because Defendants knowingly engaged in a fraudulent scheme to conceal the truth about its asbestos products, none of the statements regarding the viability of the lawsuits against the Company could have possibly been in good faith. That type of circular reasoning is insufficient to satisfy the Supreme Court's decision in *Omnicare*. Notably, even assuming as true that there was

asbestos in J&J's Talc Products, the Company may very well have defenses to the lawsuits premised on other bases such as lack of causation, or procedural issues occurring at trial.

Hall v. Johnson & Johnson, No. 18-1833, 2019 WL 7207491, at *19 (D.N.J. Dec. 27, 2019), (referring to the standard for actionable opinions set forth in *Omnicare, Inc. v. Laborers Dist. Council Constr. Indus. Pension Fund*, 575 U.S. 175 (2015)). The *Johnson & Johnson* court thus found the company's litigation-based statements inactionable under the Exchange Act. See *Axar Master Fund, Ltd. v. Bedford*, 308 F. Supp. 3d 743, 757 (S.D.N.Y. 2018) (finding litigation-based statements generally denying the allegations against the company inactionable opinions).

The same is true here. Exchange Act Plaintiffs make the same argument as the *Johnson & Johnson* plaintiffs—that Exchange Act Defendants' statements about the Willowbrook EO litigation were false and misleading because they did not disclose “the potential significant risk of an adverse outcome at trial” based on Sotera's history of inadequate EO emissions controls. (ECF No. 24, PageID #508; 516; 520; 522). Unlike *Johnson & Johnson*, where numerous, large verdicts preceded the company's litigation-based statements, all of Sotera's litigation-based statements were made prior to the *Kamuda* verdict; they are just as much, if not moreso than the *Johnson & Johnson* defendants' statements, “opinions regarding the success of the litigation, rather than statements of fact.” *Johnson & Johnson*, 2019 WL 7207491, at *19. Sotera's denials of the claims against it and promises to defend against those claims are the same types of statements found to be inactionable opinions in *Johnson & Johnson* and *Bedford*. Exchange Act Plaintiffs do not allege that Sotera was *not* vigorous in its defense of that litigation. Therefore, Sotera's general denials of the litigation claims, vows to defend itself against them, and statements regarding a contingency reserve are inactionable.

Furthermore, Sotera's more specific litigation-based statements are protected by the PSLRA safe harbor because, at minimum, they were plainly "forward-looking" alongside meaningful, cautionary language. Officer Defendants repeatedly reminded investors that, while Sotera felt comfortable in its position in the Willowbrook EO litigation, the ultimate decision in those cases would be made by a jury, "and there is risk associated with that." (ECF No. 24, PageID #509). At the September 21, 2021 Virtual JP Morgan 12th Annual U.S. All Stars Conference, Petras told those in attendance that he did not believe Sotera's facilities caused the cancer at issue in the Willowbrook EO litigation, but Sotera still had to prove that fact at the upcoming trials. (*Id.* at PageID #523). Petras made a similar statement during the Q4 2021 earnings call (*id.* at PageID #530), the March 22, 2022 Keybank Capital Markets Life Sciences & MedTech Forum (*id.* at PageID #531), and the May 17, 2022 RBC Capital Markets Healthcare Conference (*id.* at PageID #536). Mere months before the *Kamuda* verdict, Petras again reminded investors that the outcome of the Willowbrook EO litigation was uncertain; he told them that if Sotera did not "get the results [it] want[s], there will be an appeal." (*Id.* at PageID #537).

Construing the facts in Exchange Act Plaintiffs' favor as the Court must, these statements are all forward-looking, and they all include meaningful, cautionary language that cabins them within the PSLRA safe harbor. Far from "boilerplate," Sotera's executives were careful about the way they spoke about the litigation, consistently reminding investors that the Willowbrook EO litigation cases were going in front of juries and that Sotera's ultimate success would be in the hands of the courts. These are the very kinds of statements that the PSLRA safe harbor is meant to protect. As such, Exchange Act Plaintiffs have failed to satisfy their burden to show that these statements are false or misleading.

e. Health-and-Safety and Emissions-Based Statements

Exchange Act Plaintiffs allege that Exchange Act Defendants' statements about EO emissions and Sotera's commitment to health and safety "were false and misleading because they hid the reality about Sotera's long-standing failure to operate safely and in compliance." (*Id.* at PageID #442). The Court finds that information about the potential risks of EO sterilization were available to investors prior to the *Kamuda* verdict, and the Complaint fails to allege with particularity any 'inaccurate, incomplete or misleading prior' statements; many of the EO-emissions and health-and-safety statements constitute inactionable corporate "puffery." *City of Monroe Emps. Ret. Sys. v. Bridgestone, Inc.*, 399 F.3d 651, 669 (6th Cir. 2005).

First, both parties cite *Bridgestone* regarding Sotera's generalized statements about EO emissions and Sotera's health and safety commitments. (ECF No. 32, PageID #1495; ECF No. 33, PageID #1531). Relevant here, the *Bridgestone* plaintiffs claimed that it was false and misleading for the company to promote its confidence in its tires when the company had "specific, adverse information undermining the truth of those statements"; the tires had been the subject of dozens of products liability lawsuits, eventually leading to a large-scale recall. *Bridgestone*, 399 F.3d at 670. The company said it sold "the best tires in the world"; it had "no reason to believe there is anything wrong with" its tires; the tires demonstrated "global consistent quality"; that "rigorous testing under diverse conditions . . . helps ensure reliable quality"; that there was a "high regard among automakers for our strengths in product quality;" that the company had "full confidence" in its tires and "high customer satisfaction with the quality and reliability of those tires"; and that the company manufactured "safe tires." *Id.* at 670–71.

The Sixth Circuit found that these statements were "loosely optimistic statements insufficiently specific for a reasonable investor to 'find them important to the total mix of

information available.” *Id.* at 671. The statements “lacked a standard against which a reasonable investor could expect them to be pegged; such statements describing a product in terms of ‘quality’ or ‘best’ or benefitting from ‘aggressive marketing’ are too squishy, too untethered to anything measurable, to communicate anything that a reasonable person would deem important to a securities investment decision.” *Id.* (citing *Longman v. Food Lion, Inc.*, 197 F.3d 675, 684 & n.2 (4th Cir. 1999) (concluding that the statements that “Food Lion is one of the best-managed high growth operators in the food retailing industry” and that it provided its employees with “some of the best benefits in the supermarket industry” were “immaterial puffery”); *San Leandro Emergency Med. Grp. Profit Sharing Plan v. Phillip Morris Cos.*, 75 F.3d 801, 811 (2d Cir. 1996) (holding that a company’s statement that it was “optimistic” about its earnings and “should deliver income growth consistent with its historically superior performance” was non-actionable “puffery”)).

Like *Bridgestone*, Sotera also made statements that constitute “puffery.” Sotera claimed it has a “proactive environmental health and safety (“EH&S”) program and a culture of safety and quality across all business units” (ECF No. 24, PageID #505); that it had “always been on the forefront and a leader in operating these facilities and with the emission control systems that have been in place” (*id.* at PageID #509); that its EO emissions controls “are world leading in many aspects” (*id.* at PageID #530); that Sotera is committed to its mission of “Safeguarding Global Health” and strives “to ensure healthy lives and promote well-being for people around the world” (*id.* at PageID #532); that, even if Sotera ended up significantly overperforming new EPA regulations, “[T]o us, it’s the right thing to do. So it doesn’t matter. . . . We have the most advanced controls in the industry” (*id.* at PageID #536); and that Sterigenics “is leading the industry in recent [EO] enhancements” (*id.* at PageID #541).

These statements lack a standard against which a reasonable investor can compare and provide no indicia that they are data based. That these statements were made “in the context of hundreds of lawsuits that threatened the Company’s very existence . . . arising out of its failure to comply with regulations and permits” (ECF No. 32, PageID #1495) does not change the unlikelihood that a reasonable investor would rely upon them; like *Bridgestone*, these statements are simply too malleable to be considered anything more than corporate optimism to a reasonable investor. As immaterial “puffery,” these statements are inactionable.

Moving on to more specific EO-emissions and health-and-safety statements, Exchange Act Plaintiffs fail to allege with particularity that they are false. Unlike the *Johnson & Johnson* defendants, for example, who denied that cosmetic talc presented any dangers to consumers, 2019 WL 7207491, at *5, Sotera never denied that EO presents potential health and environmental risks. In the IPO Prospectus, Sotera informed investors that “***Safety risks associated with the use and disposal of potentially hazardous materials, such as EO and Co-60, may result in accidents or liabilities that materially affect our results of operation.***” (ECF No. 31-3, PageID #750). Sotera also warned that “[p]***otential health risks associated with the use of EO may subject us to future liability claims and other adverse effects.***” (*Id.* at PageID #751). This included EO’s carcinogenic potential, as well as its flammable and explosive nature. (*Id.*). Sotera’s 2020 Form 10-K and January 11, 2022 Form 8-K both acknowledge that the company has “experienced instances of emissions exceeding applicable standards, none of which we believe were material.” (ECF No. 24, PageID #505; 506).

Petras acknowledged to investors during the 2021 Q4 earnings call, while touting the success of the Atlanta facility’s 99.99% EO emissions capture rate, “We’ve already put improvements into another couple of facilities that are near completion and then ***others that are***

falling behind in that same path.” (*Id.* at PageID #509–10) (emphasis added). Petras also told the attendees of the J.P. Morgan 40th Annual Healthcare Conference that the company was “ramping up construction and renovation efforts,” and anticipated those efforts to last two years into the future. (*Id.* at PageID #547). To the extent that Sotera’s Investor Web Portal provided statements regarding generally accepted science and scientific studies showing a reduced connection between EO exposure and cancer risk (*id.* at PageID #544), Plaintiffs do not make any argument in their opposition to the motion to dismiss that these statements were false, nor grounds for the belief in their falsity.

Absent from any of these statements is a claim that Sotera was consistently capturing all EO emissions in every sterilization facility it operates; rather, Sotera’s executives consistently told investors that higher EO emissions capture was an ongoing effort. Exchange Act Plaintiffs do not allege that Sotera was *not* making those efforts. Exchange Act Plaintiffs therefore failed to meet their burden to show under Rule 9(b) and the PSLRA that these statements are false and misleading with particularity.

f. Allegations Related to Sotera’s Failures to Make Necessary Disclosures

With regard to material omissions in a legal disclosure obligation, Exchange Act Plaintiffs assert three in support of their Section 10(b) and Rule 10b-5 claims relating to Sotera’s disclosure obligations under Items 303, 105, and 307. (ECF No. 24, PageID #552–57). Item 303 of SEC Regulation S-K, 17 C.F.R. § 229.303(b)(2)(ii) requires a registrant to “[d]escribe any known trends or uncertainties that have had or that are reasonably like to have a material favorable or unfavorable impact on net sales or revenues or income from continuing operations.” Item 105 requires that a prospectus include a section titled “Risk Factors,” which shall contain “a discussion of the material factors that make an investment in the registrant or offering speculative or risky.” 17 C.F.R. §

229.105(a). And Item 307 requires the registrant’s principal executive and principal financial officers (or persons performing similar functions) to disclose conclusions “regarding the effectiveness of the registrant’s disclosure controls and procedures.” 17 C.F.R. § 229.307.

A failure to disclose information required to be disclosed by an affirmative disclosure obligation can support a Rule 10b-5(b) claim when “the omission renders affirmative statements made misleading.” *Macquarie Infrastructure Corp. v. Moab Partners, L.P.*, 601 U.S. 257, 265 (2024). This rule covers “half-truths;” although 10b-5(b) “does not proscribe pure omissions,” it nonetheless requires a company that speaks on a topic to include material facts necessary to make that statement “not misleading.” *Id.* at 264. Thus, a company’s disclosure statements cannot omit facts known to the company that renders the disclosure misleading. *Id.*

1. Sotera, Exchange Act Officer Defendants, and Exchange Act Selling Shareholder Defendants did not violate Sotera’s disclosure requirements under Item 303 or Item 105 of Regulation S-K.

Exchange Act Plaintiffs’ Item 303 claim alleges that Sotera, Exchange Act Officer Defendants, and Exchange Act Director Defendants were aware of Sotera’s “trend” of repeat safety violations that include toxic EO exposure of Sotera’s employees and those living in communities surrounding its facilities (*Id.* at PageID #553). Sotera, Exchange Act Officer Defendants, and Exchange Act Selling Shareholder Defendants then failed to report this known trend of “quality and safety control weaknesses” regarding its compliance with EO regulations and internal safety procedures “that were likely to result in serious problems for the Company, both financial and otherwise.” (*Id.* at PageID #554).

Exchange Act Plaintiffs’ Item 105 claim is based on Sotera’s Forms 10-K and 10-Q, which purportedly “contained materially false or misleading representations about *potential* regulatory and legal risks when, in fact, such risks were *then existing*.” (*Id.* at PageID #554). Exchange Act

Defendants counter that Exchange Act Plaintiffs concede Sotera's disclosure of certain potential risks related to EO; Exchange Act Plaintiffs' claim is instead based on Sotera's failure to disclose the "true risk of liability" based on Sotera's "failure to maintain proper safety controls." (ECF No. 31-3, PageID #701 (citing ECF No. 24, PageID #554–56)). Exchange Act Plaintiffs' claims under Item 303 and Item 105 rely upon the same set of facts, and thus, the Court addresses them together.

While Exchange Act Plaintiffs need not establish scienter to support these claims, Item 303's strict liability only attaches when the defendant fails "to make forward-looking projections regarding information *known* to the registrant." *J & R Mktg., SEP v. Gen. Motors Corp.*, 549 F.3d 384, 392 (6th Cir. 2008) (citing 17 C.F.R. § 229.303(a)(1), (2)(ii), 3(ii)) (emphasis added). Item 105 imposes a similar duty: it requires disclosure of **known** "material [risk] factors that make an investment in the registrant or offering speculative or risky." *Kolominsky v. Root*, 100 F.4th 675, 685 n.4 (6th Dist. 2024) (quoting 17 C.F.R. § 229.105(a)). "Risk factors that are not 'reasonably likely to be material under Item 303 are not material factors that render an offering speculative or risky under Item 105.'" *Id.* (quoting *Hutchison v. Deutsche Bank Sec. Inc.*, 647 F.3d 479, 484 n.4 (2d Cir. 2011) (referencing Item 503(c), which was relocated to Item 105)).

This does not include information that is merely "knowable"; a plaintiff's Item 303 and Item 105 claims must be based on actual, present knowledge. *J& R Mktg.*, 549 F.3d at 391–92; *see In re Honest Co. Sec. Litig.*, 615 F. Supp.3d 1149, 1158 (C.D. Cal. 2022) (requiring a showing of actual, present knowledge to support an Item 105 claim). Similarly, while Regulation S-K governs the disclosure of "known historic trends," it "does not provide a basis of liability where a corporation fails to 'disclose the future.'" *Terenzini v. GoodRX Holdings, Inc.*, No. LA CV 20-11444, 2022 WL 2189592, at *4 (C.D. Cal. June 9, 2022) (citing *In re Verifone Sec. Litig.*, 784 F. Supp. 1471, 1483 (N.D. Cal. 1992), *aff'd* 11 F.3d 865 (9th Cir. 1993)). At its core, Item 303

requires disclosure of “presently known data which *will* impact future operating results, such as *known* future increases in costs of labor of materials”; it does not require disclosure of strictly forward-looking information. *Walker v. L Brands, Inc.*, No. 2:19-cv-3186 & 2:19-cv-3961, 2020 WL 6118467, at *15 (S.D. Ohio Oct. 16, 2020) (citing *In re Sofamor*, 123 F.3d 394, 402 (6th Cir. 1997)). The same is true in relation to Item 105; the risk factors reasonably likely to have a material effect on the registrant’s financial condition or result of operation must be presently known, rather than merely speculative. *In re Honest Co. Sec. Litig.*, 615 F. Supp.3d at 1158.

Exchange Act Defendants rely on *GoodRx* in support of their argument against Exchange Act Plaintiffs’ Item 303 and Item 105 claims. There, stockholders of GoodRx alleged that the company had actual knowledge that a major competitor, PrimeRx (an arm of Amazon), would disrupt GoodRx’s grip on the direct-to-consumer prescription drug pricing market; GoodRx was charged with this knowledge because PrimeRx’s launch included a partnership with InsideRx—a company of which GoodRx was a founding partner. *GoodRx*, 2022 WL 2189592, at *1, *4. The problem was that GoodRx’s IPO had launched “well above its per share offering price,” in part based on GoodRx’s statements in its offering materials and thereafter to have a monopoly of sorts on the market. *Id.* at *1. The stockholders sued, claiming that GoodRx should have disclosed the material risk of competition from PrimeRx’s launch, due to the knowledge it must have had as a founding member of InsideRx. *Id.* at *1.

The *GoodRx* court dismissed this claim—twice. *Id.* at *5. The first time, the court explained, “Without facts indicating concrete knowledge of Amazon’s plans, any lack of disclosure here would be merely a failure to ‘disclose the future.’” *Id.* On the stockholder’s second attempt, the court further explained that the stockholders presented “only circumstantial evidence regarding GoodRx’s business relationship with Amazon subsidiaries,” rather than evidence of GoodRx’s

actual knowledge of PrimeRx’s launch. *Id.* The stockholder’s failure to allege GoodRx’s actual knowledge of the risk of competition also led to dismissal of the stockholders’ Item 105 claim. *Id.* The matter was, therefore, dismissed.

Like the *GoodRx* plaintiffs, the thrust of Exchange Act Plaintiffs’ Complaint is that Sotera did not disclose the future—Sotera did not disclose its purportedly woeful compliance with EO regulations that led to the *Kamuda* jury finding against Sotera, including findings of willful and wanton conduct. Along the same vein, Sotera also did not disclose certainty of the *Fornek* verdict that absolved Sotera of the claims of wrongdoing against it. The Complaint does not allege that Exchange Act Defendants actually knew that Sotera would lose (or win) either case based on actual knowledge that it did (or did not) cause the plaintiffs’ cancer in those cases; rather, like the *GoodRx* plaintiffs, Exchange Act Plaintiffs allege that Sotera *should have known* that its quality control weaknesses would subject Sotera to future “serious problems,” and that its “potential risks” were, in fact, imminent future liabilities.⁷ Sotera’s risk of adverse judgments—which it repeatedly disclosed in its SEC filings and in Petras’s and Leffler’s statements to investors—was not the kind of “trend” of which Item 303 requires disclosure; Sotera’s *Kamuda* loss, even following Sotera’s payment of “thousands of dollars in safety violations” (ECF No. 32, PageID #1497; ECF No. 24, PageID #553), was not as concrete as something like a future cost-of-labor increase based on increased minimum wage or a future supply-chain problem based on a current supplier’s closure.

⁷ Exchange Act Plaintiffs claim that Exchange Act Selling Shareholder Defendants Warburg and GTCR had actual knowledge of Sotera’s “long history and ongoing failure to operate safely, comply with applicable regulations, and address the attendant liability, business and reputational risks that Sotera faced.” (ECF No. 24, PageID #580). Exchange Act Plaintiffs point to Cunningham’s testimony during the *Kamuda* litigation that GTCR knew about Sotera’s regulatory violations as a product of GTCR’s due diligence performed prior to GTCR’s acquisition of Sotera. (*Id.* at PageID #580–81). Notably, GTCR’s acquisition of Sotera occurred in March 2011, which is more than nine years before the beginning of the Class Period. (*Id.* at PageID #453). These allegations are far too old to bear on whether Warbug or GTCR had actual knowledge that statements made in Sotera’s Class Period 10-Ks and 10-Qs were false. *See In re Omnicare, Inc. Sec. Litig.*, 769 F.3d 455, 481 (6th Cir. 2014) (finding that knowledge gained between 2000 and 2005 shed “little light on whether the Form 10-K statements regarding practices in 2007 and later were made with actual knowledge of their falsity”).

Furthermore, the “potential risks” Sotera disclosed were precisely that—risks that may or may not materialize in the future, none of which could have been knowable before they happened. As far as Defendants knew, the outcome of the Willowbrook EO litigation could have gone either way; after all, Sotera lost *Kamuda* and won *Fornek*. The “Risk Factor Summary” in the Form 10-Ks described in the Complaint paint an accurate picture of this uncertainty, disclosing both actual risk and the unpredictability of how that actual risk would impact the company: Sotera informed investors that its operations were “subject to numerous risks, factors and uncertainties, including those outside our control, that could cause our actual results to be harmed, including risks regarding the following: . . . [I]mpact and outcome of current and future legal proceedings and liability claims, including lawsuits alleging personal injury[.]” (ECF No. 24, PageID #554). Sotera then disclosed that it was dealing with some of those actual risks in various court proceedings, none of which had yet resulted in a finding of wrongdoing by Sotera. (*Id.* at PageID #556). The Form 10-Ks also disclosed the actual risk associated with unknown, future changes in the regulatory environment. (*Id.* at PageID #555). The 10-Ks likewise disclosed that Sotera has “experienced instances of emissions exceeding applicable standards,” and had “made proactive, voluntary investments to enhance emissions controls” beyond an apparently lesser, prior standard. (*Id.* at PageID #505–06; 528).

Similar disclosures appear throughout Sotera’s quarterly 10-Qs. For example, the May 13, 2021 Q1 2021 Form 10-Q disclosed that Sotera had not taken a contingency reserve related to pending regulatory and legal actions “because of the uncertainties related to the outcome and/or the amount or range of loss.” (*Id.* at PageID #516). In fact, Sotera stated that it was “not possible” to estimate that potential loss but went on to assert that it did “not expect that the ultimate resolution of pending regulatory and legal matters in future periods . . . will have a material effect on our

financial condition or results of operations.” (*Id.*; *see id.* at PageID #534 (quoting the same language in Sotera’s May 5, 2022 Q1 2022 Form 10-Q)). The August 12, 2021 Q2 Form 10-Q provided a detailed update on the New Mexico AG regulatory matter, including details about the preliminary injunction to which Sotera was subject, and the efforts Sotera was making to comply with that order. (*Id.* at PageID #519).

Upon review of these filings, Sotera disclosed the actual risks it knew about. Sotera could not, however, disclose the inevitability of risks being realized later, because Sotera could not know the future. Exchange Act Plaintiffs failed to base their Item 303 and Item 105 claims on actual knowledge of imminently certain risk possessed by Sotera and/or its leadership. Sotera’s purported Item 303 and Item 105 violations based on certainty of future risks coming to fruition of which Sotera, Exchange Act Officer, and Exchange Act Selling Shareholder Defendants “should have known” cannot support Exchange Act Plaintiffs’ claim under Rule 10b-5 of the Exchange Act.

2. Sotera, Exchange Act Officer Defendants, and Exchange Act Selling Shareholder Defendants did not violate Sotera’s disclosure requirement under Item 307.

Exchange Act Plaintiffs allege that Petras’s and Leffler’s signatures on Sotera’s Form 10-Ks violated Item 307 because the Form 10-K failed to disclose that they:

turn[ed] a blind eye to or condon[ed] willful conduct on the part of its workers to improperly release EtO gas into the communities, and the resulting true risk of liability in connection with hundreds of EtO tort lawsuits filed against it, which resulted in a single case securing a \$363 million verdict against Defendants and the finding of ‘willful and wanton’ conduct on the part of Defendants in terms of their failure to adequately safeguard the local community from the overexposure of EtO gas.

(ECF No. 24, PageID #557–58). Exchange Act Plaintiffs also claim that Sotera did not enhance emissions controls after the Willowbrook facility’s closure, and continued to operate sterilization facilities that emit dangerous levels of EO gas. (*Id.* at PageID #558).

Exchange Act Plaintiffs argue that liability attaches to Sotera, Exchange Act Officer Defendants, and Exchange Act Selling Shareholder Defendants because Petras and Leffler “certified that controls were in place when they were not,” leading to the omission of material information from SEC filings. However, this Court has already found that Plaintiffs failed to plausibly allege any actionable material misstatements in any of the SEC filings described in the Complaint. The Court has also found that Sotera did not breach its disclosure requirements by omitting material information necessary to render those disclosures not misleading under Items 303 and 105 of Regulation S-K. Having failed to identify any material omission committed by these Defendants, this argument fails. *See Walker v. L Brands, Inc.*, No. 2:19-cv-3186, 2020 WL 6118467, at *17 (S.D. Ohio Oct. 16, 2020) (rejecting Item 307 argument following finding that the plaintiff failed to identify any material omissions by the defendants in relevant Form 10-Qs).

The Court cannot locate any allegations in the Complaint that are actionable under Section 10(b) and Rule 10b-5 to support either Count One or Two. Having failed to plead actionable misstatements or omissions with particularity, Counts One and Two must be dismissed.⁸ Consequently, Exchange Act Plaintiffs’ “control person” claim under Section 20(a) of the Exchange Act, which must be predicated on a primary violation of the Exchange Act, also requires dismissal. *Ind. State Dist. Council of Laborers & Hod Carriers Pension & Welfare Fund v. Omnicare, Inc.*, 585 F.3d 935, 947 (6th Cir. 2009).

⁸ Having determined that Exchange Act Plaintiffs failed to allege actionable misstatements and omissions with particularity, the Court will not address the parties’ extensive briefing on the issue of scienter. The Court recognizes that the issue of scienter is a significant one, but such discussion will not alter the Court’s conclusion that Exchange Act Plaintiffs have not met their burden to adequately plead Counts One and Two.

B. Securities Act Plaintiffs Have Standing to Assert Their Section 12(a)(2) Claim

Moving on to the claims brought under the Securities Act, Count Five brings a claim against Sotera, the Securities Act Selling Shareholders, and the Underwriter Defendants under Section 12(a)(2) of the Securities Act. Section 12(a)(2) provides:

(a) In general

Any person who—

...

(2) offers or sells a security . . . , by the use of any means or instruments of transportation or communication in interstate commerce or of the mails, by means of a prospectus or oral communication, which includes an untrue statement of material fact or omits to state a material fact necessary in order to make the statements, in light of the circumstances under which they were made, not misleading (the purchaser not knowing of such untruth or omission), and who shall not sustain the burden of proof that he did not know, and in the exercise of reasonable care could not have known, of such untruth or omission,

shall be liable, subject to [a showing of loss causation], to the person purchasing such security from him, who may sue either at law or in equity in any court of competent jurisdiction, to recover the consideration paid for such security with interest thereon, less the amount of any income received thereon, upon the tender of such security, or for damages if he no longer owns the security.

15 U.S.C. 77l(a)(2).

Securities Act Defendants argue that Securities Act Plaintiffs lack standing because the Complaint does not allege that they purchased shares from statutory sellers. (ECF No. 31-1, PageID #716). Indeed, only “statutory sellers” are liable under Section 12(a)(2); a “statutory seller” is one who “either transferred title to the purchaser or successfully solicited the transfer for financial gain.” *In re EveryWare Glob., Inc. Sec. Litig.*, 175 F. Supp. 3d 837, 867 (S.D. Ohio 2016); see Thomas Lee Hazen, *The Law of Securities Regulation* 312 (8th ed. 2021) (explaining that “section 12(a)(2) is limited to liability of sellers and thus imposes a strict privity requirement”).

“In other words, Section 12(a) ‘imposes liability on only the buyer’s immediate seller; remote purchasers are precluded from bringing actions against remote sellers.’” *In re EveryWare*, 175 F. Supp. 3d at 867 (citing *Pinter v. Dahl*, 486 U.S. 622, 644 n.21 (1988)). Statutory sellers include “those who have (1) passed title, or other interest in the security, to the buyer for value, or (2) successfully solicited the purchase of a security, motivated at least in part by a desire to serve his own financial interests or those of the securities’ owner.” *Gaynor v. Miller*, 273 F. Supp. 3d 848, 861 (E.D. Tenn. 2017) (citing *In re Regions Morgan Keegan Sec., Derivative & ERISA Litig.*, Nos. 2:09-2009 & 2:07-cv-02830, 2012 WL 12875982, at *9 (W.D. Tenn. Mar. 30, 2012); *In re Morgan Stanley Info. Fund Sec. Litig.*, 592 F.3d 347, 360 (2d Cir. 2010)).

Since Section 12(a)(2) only applies to purchases made through initial offerings, “[a] complaint that alleges that the plaintiff purchased securities ‘pursuant and/or traceable to’ the offering documents that contain falsities is not sufficient to establish Section 12 standing.” *Gaynor*, 273 F. Supp. 3d at 861 (citing *In re Lehman Bros. Sec. & ERISA Litig.*, 799 F. Supp. 2d 258, 310–11 (S.D.N.Y. 2011)); *see also Gustafson v. Alloyd Co.*, 513 U.S. 561, 576 (1995) (holding that Section 12(a)(2), through use of the term “prospectus,” relates only to “public offerings by issuers and their controlling shareholders”, and not to aftermarket trading). Instead, the plaintiff “must allege they purchased the securities ‘pursuant to’ the allegedly misleading offering documents.” *Me. State Ret. Sys. v. Countrywide Fin. Corp.*, No. 2:10-CV-0302, 2011 WL 4389689, at *11 (C.D. Cal. May 5, 2011).

Securities Act Plaintiffs initially allege that they “purchased Sotera common stock ***in or traceable to*** the IPO and SPO, during the Class Period.” (ECF No. 24, PageID #598) (emphasis added). In Count Five, however, Securities Act Plaintiffs allege that “Class members within the scope of this Count acquired Sotera shares ***pursuant to*** the defective IPO Offering Materials and/or

SPO Offering Materials.” (*Id.* at PageID #622). This allegation is sufficient to allege that Securities Act Selling Shareholders and Underwriter Defendants are “statutory sellers.” The Court finds that Securities Act Plaintiffs have standing to bring their Section 12(a)(2) claim.

C. Securities Act Plaintiffs Fail to Adequately Allege the IPO and/or SPO Offering Materials Contained an Untrue Statement of Material Fact or Omission of Material Fact Necessary in Order to Make the Statements, in Light of the Circumstances Under Which They Were Made, Not Misleading, Requiring Dismissal of their Section 11 and Section 12(a)(2) claims.

Having determined that Securities Act Plaintiffs have standing to assert their Section 12(a)(2) claim, the Court now considers the claim’s substance. Since Securities Act Plaintiffs’ Section 11 and Section 12(a)(2) claims rest on the same purported false and misleading statements and omissions, the Court will consider the Securities Act Plaintiffs’ arguments regarding these claims together. *See Kolominsky v. Root*, 100 F.4th 675, 684 (6th Cir. 2024) (explaining that Section 11 and Section 12 claims may be considered together when they rely on the same statements).

“Claims under section 11 and 12(a)(2) are . . . Securities Act siblings with roughly parallel elements.” *Sohol v. Yan*, No. 1:15-cv-393, 2016 WL 1704290, at *6 (N.D. Ohio Apr. 27, 2016) (quoting *In re Morgan Stanley Info. Fund Sec. Litig.*, 592 F.3d 347, 359 (2d Cir. 2010)). “So long as a plaintiff establishes one of the three bases for liability under these provisions—(1) a material misrepresentation; (2) a material omission in contravention of an affirmative legal disclosure obligation; or (3) a material omission of information that is necessary to prevent existing disclosures from being misleading—then . . . the general rule is that an issuer’s liability . . . is absolute.” *Id.* (quoting *Litwin v. Blackstone Grp., L.P.*, 634 F.3d 706, 715–16 (2d Cir. 2011); 15 U.S.C. §§ 77k(a), 77l(a)(2)). Like Rule 10b-5 claims, materiality of a misleading statement or omission “depends on the significance the reasonable investor would place on the withheld . . .

information.” *Kolominsky*, 667 F. Supp. 3d at 698 (citing *Benzon v. Morgan Stanley Distribs.*, 420 F.3d 598, 609 (6th Cir. 2005)). The critical question for the Court is whether such information “would have significantly altered the total mix of information made available.” *Id.* (quoting *Benzon*, 420 F.3d at 609).

1. *Securities Act Plaintiffs Fail to State a Material Misrepresentation or Omission in Support of Their Section 11 and Section 12(a)(2) Claims.*

The Securities Act portion of the Complaint relies upon alleged material misrepresentations and omissions contained in the IPO and SPO Offering Materials, which include the 2020 Form 10-K. The Court has already addressed many of the allegedly “actionable misstatement[s] and omission[s]” of which Securities Act Plaintiffs complain. They again point the Court to Sotera’s claims that its EO facilities “often outperform the regulatory standards that we are required to meet” (ECF No. 24, PageID #608); that Sotera “consistently meets and outperforms regulatory emissions control requirements” and had been “investing in additional voluntary controls” (*id.* at PageID #609); that Sotera had not taken a contingency reserve related to regulatory and legal actions pending against it (*id.* at PageID #611; 615); that Sotera denied causing the cancer in the Willowbrook litigation and vowed to vigorously defend against it (*id.* at PageID #612); and that Sotera has a “proactive environmental health and safety (‘EH&S’) program and a culture of safety and quality across all business units” (*id.* at PageID #613). The Court has already found that these statements are either inactionable or inadequately pleaded. (*See supra* at 50–54; 59–60; 62–64). Because the Securities Act claims sound in fraud, those conclusions apply to these claims.

Securities Act Plaintiffs also take issue with Sotera’s claim of “significant technical expertise” and its “highly trained and skilled workforce” that is used to manage Sotera’s “strict regulatory requirements safely and effectively.” (ECF No. 24, PageID #608). Securities Act Plaintiffs point to Sotera’s claim that it exercises “operational discipline . . . to manage intricate

quality assurance and EH&S programs,” in order to give its customers “confidence that we are the best partner to support them in their businesses.” (*Id.*). Further, Sotera claimed, “We work closely with our customers, the FDA and others to consider enhanced EO cycle design and process that would reduce EO emissions from the EO sterilization process to as close to zero as reasonably possible.” (*Id.* at PageID #608–09). The IPO Offering Materials also state that Sotera “employs engineering and procedural controls and pollution control equipment” in order to “reduce the risk of noncompliance.” (*Id.* at PageID #609).

Securities Act Plaintiffs allege that these statements were “untrue and misleading” because

[i]n truth, Sotera and its predecessors were aware of the carcinogenic risk that EtO posed to the surrounding communities since at least the early 1980s, yet chose not to employ adequate and effective EtO emissions control systems at its sterilization facilities and often subverted whatever control systems the Company did have, allowing dangerous amounts of toxic EtO fumes to pollute the air surrounding those facilities and exposing people living in the adjacent communities to significantly increased cancer risks and the Company to an increased headline risk, risk of regulatory scrutiny, and liability from hundreds of EtO related lawsuits.

(*Id.* at PageID #610). Securities Act Defendants counter that the statements at issue amount to corporate optimism and “puffery.” (ECF No. 31-1, PageID #706).

The Court finds that these allegations do not meet the particularity requirement of Fed. R. Civ. P. 9(b). Securities Act Plaintiffs allege no facts that suggest Sotera did *not* employ “significant technical expertise” or a “highly trained and skilled workforce” that included “engineering and procedural controls and pollution control equipment.” (*See* ECF No. 24, PageID #608). Sotera’s purported knowledge of EO’s carcinogenic risk and the adequacy of its control systems are unrelated to whether Sotera in fact hired skilled and knowledgeable workers. Similarly, Securities Act Plaintiffs do not explain *why* it was false and misleading for Sotera to claim that it works with its customers and regulators in an effort to reduce its emissions to near zero. Other portions of the

Complaint establish that Petras corroborated this statement repeatedly, telling investors that Sotera had achieved 99.99% capture of EO emissions in Atlanta. (*Id.* at PageID #502; 509; 517; 518). None of the Plaintiffs in this case have presented particularized facts refuting that claim.

Regarding Sotera's statements relating to "operational discipline," Sotera's "intricate quality assurance and EH&S programs," and Sotera's efforts to be its customers' "best partner to support them in their businesses," these statements are corporate optimism and "puffery" upon which no reasonable investor would rely. (*See supra* at 61–63); *City of Monroe Emps. Ret. Sys. v. Bridgestone, Inc.*, 399 F.3d 651, 671 (6th Cir. 2005) (explaining that statements constituting "puffery" "lacked a standard against which a reasonable investor could expect them to be pegged."). Therefore, none of the purported misstatements or omissions alleged in the Securities Act portion of the Complaint can be used to support Securities Act Plaintiffs' Section 11 or Section 12(a)(2) claims.

2. Securities Act Plaintiffs fail to show that Securities Act Defendants and Underwriter Defendants violated Items 303, 105, or 307

Like the Exchange Act claims related to Items 303 and 105, the Securities Act claims are not supported by any additional allegations regarding the Securities Act Defendants' or Underwriter Defendants' "actual knowledge" of known trends and potential risks that make Sotera's annual 10-Ks and quarterly 10-Q's misleading. No allegations at all differentiate any of Sotera's directors from one another. To the extent that Directors Klee and Petrella are included in the Securities Act claims but not the Exchange Act claims, Securities Act Plaintiffs do not make any showing of their relevant knowledge to differentiate them from the analysis already performed regarding the Exchange Act Selling Shareholders (which includes Directors Cunningham, Donnini, Mihas, Chen, Geveda, and Neary). Thus, the Court comes to the same conclusion regarding Directors Klee and Petrella, and finds that Securities Act Plaintiffs failed to adequately

allege that Directors Klee and Petrella actually knew about trends and risks that Sotera failed to disclose under Items 303 and 105. (*See supra* at 68–70).

The Court must come to the same conclusion regarding the Underwriter Defendants. Securities Act Plaintiffs’ allege that the Underwriter Defendants were “responsible for ensuring the truthfulness and accuracy of the various statements contained in or incorporated by reference into the IPO Offering Materials and SPO Offering Materials.” (ECF No. 603–06). Beyond this, no specific allegations against these defendants are alleged. The Court therefore cannot find that these defendants actually knew about trends or risks that were not disclosed in the IPO and SPO Offering Materials. (*See supra* at 68–70).

Regarding Item 307, this Court has already found that the statements described in the Securities Act Complaint do not amount to material misrepresentations or omissions. (*See supra* at 71). Since Securities Act Plaintiffs have failed to plead actionable, material misstatements and omissions related to the IPO and SPO Offering Materials, this claim must also fail.

3. *Securities Act Plaintiffs’ “control person” claim also fails.*

Finally, Count Six alleges a “control person” claim under Section 15 of the Securities Act. This provision grounds liability of control persons “on the corporation being found liable under Section 11 or 12.” *J & R Mktg., SEP v. Gen. Motors Corp.*, 549 F.3d 384, 398 (6th Cir. 2008). Having failed to establish any primary violations of the Securities Act, Plaintiffs’ “control person” claim under Section 15 of the Securities Act must also be dismissed.

IV. CONCLUSION

Both Exchange Act Plaintiffs and Securities Act Plaintiffs failed to plead actionable, material misstatements or omissions with particularity to support their claims under § 10(b) and Rule 10b-5(a)–(c) of the Exchange Act and Section 11 and Section 12(a)(2) of the Securities Act.

As such, Counts One, Two, Four and Five must be dismissed. Having failed to adequately plead primary violations of either the Exchange or Securities Act, Plaintiffs' "control person" claims under Section 20(a) of the Exchange Act and Section 15 of the Securities Act enumerated in Counts Three and Six must also be dismissed. Accordingly, this action is **DISMISSED WITH PREJUDICE**.

IT IS SO ORDERED.

Date: March 19, 2025

A handwritten signature in cursive script, reading "Charles Fleming".

CHARLES E. FLEMING
U.S. DISTRICT COURT JUDGE